## IN THE COURT OF APPEALS OF THE STATE OF OREGON

STATE ex rel Ellen F. ROSENBLUM, Attorney General of Oregon, Plaintiff-Appellant, and

# John R. KROGER, Plaintiff,

v.

### JOHNSON & JOHNSON; McNeil-PPC, Inc.; and McNeil Healthcare, LLC, Defendants-Respondents.

Multnomah County Circuit Court 110100494; A153226

Christopher J. Marshall, Judge.

Argued and submitted July 10, 2014.

David B. Thompson, Assistant Attorney General, argued the cause for appellant. With him on the briefs were Ellen F. Rosenblum, Attorney General, and Anna M. Joyce, Solicitor General.

James T. McDermott argued the cause for respondents. With him on the brief was Ball Janik LLP.

Before Sercombe, Presiding Judge, and Haselton, Chief Judge, and Duncan, Judge.

HASELTON, C. J.

Reversed and remanded.

#### HASELTON, C. J.

The state appeals a judgment dismissing this action pursuant to the Oregon Unlawful Trade Practices Act (UTPA), ORS 646.607 and ORS 646.608, against defendants, who manufacture and distribute the over-the-counter painkiller Motrin. The state argues that the trial court, in dismissing the action under ORCP 21 A(8), erroneously concluded that the failure to disclose a known material *risk* that goods sold in Oregon may be defective is not actionable under the UTPA. We agree that the trial court so erred. *See, e.g., Caldwell v. Pop's Homes, Inc.*, 54 Or App 104, 634 P2d 471 (1981). Accordingly, we reverse and remand.

Whether a pleading fails to state ultimate facts sufficient to constitute a claim, as required under ORCP 21 A(8), is a question of law. *Hansen v. Anderson*, 113 Or App 216, 218, 831 P2d 717 (1992). When reviewing an order granting dismissal on that ground, we accept as true the facts alleged in the complaint and all reasonable inferences that may be logically deduced from the pleaded facts. *Bernards v. Summit Real Estate Management, Inc.*, 229 Or App 357, 367-68, 213 P3d 1 (2009). We state the material facts in accordance with that standard by reference to the state's operative amended complaint.

The defendants in this action are Johnson & Johnson, McNeil-PPC, Inc., and McNeil Healthcare, LLC. McNeil-PPC and McNeil Healthcare are Johnson & Johnson subsidiaries, and the three entities are in the business of manufacturing, advertising, distributing, and selling overthe-counter drugs throughout the United States, including in Oregon. In November 2008, defendants discovered that a batch of Motrin pills that had been manufactured at a Puerto Rico plant was defective—the 200-milligram pills failed to dissolve at the rate required by specifications for good manufacturing practices. The defective batch had been packaged and sold in 8-count vials. Six days after that discovery, defendants reported the dissolution failure to the FDA, but did not conduct a recall or notify wholesalers, retailers, or consumers that its 8-count vials contained potentially defective medicine.

Defendants eventually admitted that consumers who used the defective Motrin "might be receiving less than the expected dose of ibuprofen" and that its use "may lead to a worsening of pain, fever, or inflammation, all of which are very likely to be recognized by the consumer or diagnosed by a healthcare professional."

A month later, in December 2008, defendants discovered the same dissolution defect in another batch of Motrin from the same Puerto Rico plant. That second batch of defective Motrin had been sold in 8-count vials and in 24-count bottles. In notifying the FDA of its second known batch of defective Motrin, defendants disclosed that it had been sold in 8-count vials, but did not disclose that the defective pills were also sold in 24-count bottles. Defendants, again, did not recall the defective product or notify wholesalers, retailers, or consumers.

Defendants eventually determined that 88,104 units of the defective Motrin 8-counts had been distributed nationally, and identified 29 Oregon retailers who received shipments of 8-counts during the distribution window for the defective pills. Defendants did not notify those 29 Oregon retailers (or anyone else outside the state) who were selling potentially defective Motrin; nor did they disclose the defect to consumers in Oregon or elsewhere, despite their knowledge that there was a material risk that defective Motrin was on the market in Oregon.

Defendants decided not to publicly recall the product. Instead, they hired a company, Inmar CLS, to send its employees—"secret shoppers"—out to purchase the remaining Motrin 8-counts from retailers. According to McNeil Healthcare's "Director of Quality Assurance," this covert buy-back approach was "a newly created prescribed path \*\*\* which is a bit different than our typical procedures." Similarly, according to McNeil Healthcare's "Site Quality Leader" in Puerto Rico, the buy-back approach was "very different," made possible by his "good relationship" with the local FDA director, with whom he had been having "very confidential" "off the record" discussions about how to avoid a recall. However, defendants were concerned that their highly unusual buy-back project would come to the attention of other FDA personnel, who would require a public recall. Defendants were particularly concerned about "the press that will be seen" in the event of a recall.

The first phase of the buy-back project took place in March and April 2009, months after the discovery of the defective Motrin. Inmar's "secret shoppers" were explicitly ordered not to alert store personnel to the defect:

"DO NOT communicate to store personnel any information about this product. Just purchase all available product. If you are questioned by store personnel, simply advise that you have been asked to perform an audit[.]"

## (Capitalization in original.)

The project's first phase was limited in scale, designed to survey the amount of defective product on store shelves. Defendants sent secret shoppers to two stores in Oregon, and 250 stores nationwide. The goal was to obtain data that would allow defendants to prove to the FDA that all of the defective product had already been sold, so as to avoid the need for a nationwide recall. Defendants understood that, "if the data is not favorable," the FDA—once notified—would expect a nationwide recall.

Defendants commenced the second phase of the buy-back project in June 2009, this time contracting with another company, WIS International. The second phase was much larger in scale, designed as a mass "silent recall" of the potentially defective Motrin from about 5,000 stores nationwide. Again, the drafted instructions to field employees emphasized that the "recall" was to be conducted in absolute secrecy:

"You should simply 'act' like a regular customer while making these purchases. **THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!** If asked, simply state that your employer is checking the distribution chain of this product and needs to have some of it purchased for the project."

(Capitalization and boldface in original.)

During the second phase of the buy-back, WIS sent secret shoppers to 27 Oregon stores that defendants

identified as having potentially received defective product through their supply chain. Specifically, defendants knew that 828 8-count vials that *could* contain pills from the defective batches had been distributed and sold in Oregon. However, the secret shoppers were able to find and purchase only 41 units, leaving the other 787 8-count units unaccounted for. In other words, by the time defendants actually executed their secret buy-back project, 95 percent of the units distributed in Oregon that *could* have contained defective Motrin had already been sold to consumers. Yet defendants did not, at any point before or during this course of events, notify Oregon consumers or retailers that the Motrin they had purchased or sold was potentially defective.<sup>1</sup>

In July 2009, a WIS employee, who was engaged in covert purchases in Oregon and was concerned about defendants' surreptitious activities, informed the Oregon Board of Pharmacy, which, in turn, notified the FDA. By July 16, 2009, defendants were aware that the FDA expected them to conduct a publicized nationwide recall, having been so informed in writing.

Seven months later, on February 17, 2010, defendants publicly notified retailers and wholesalers of the potentially defective Motrin 24-count bottles.

Eventually, a series of FDA inspections established that McNeil-PPC's production facilities—including the Puerto Rico facility that had manufactured the defective Motrin—had failed to comply with good manufacturing practices and that drugs from those facilities were adulterated. Defendants conducted three major recalls, including the largest recall of children's medicines in the history of the FDA. A Consent Decree of Permanent Injunction entered into with the United States required destruction of Motrin 24-count bottles and third-party supervision of its manufacturing facilities for at least 60 months.

In the light of those events, the state filed this action against defendants under the UTPA, seeking civil penalties, various forms of injunctive relief, and attorney fees

<sup>&</sup>lt;sup>1</sup> The amended complaint does not allege that any of the defective Motrin was ever actually distributed to Oregon retailers or sold to Oregon consumers.

and costs. *See* ORS 646.632; ORS 646.642. In addition to alleging the facts recounted above, the amended complaint asserted four claims for relief based on various UTPA violations. The gravamen of each of those closely related claims was that defendants' misrepresentation of the risk that the product was defective constituted actionable conduct under the UTPA.

The state's first claim, brought under ORS 646.608(1)(e)—which prohibits misrepresenting the "sponsorship, approval, characteristics, ingredients, uses, benefits, quantities or qualities" of goods—alleged violations stemming from defendants' continued advertising, promotion, and offering for sale potentially defective Motrin to consumers and retailers in Oregon. In so doing, the complaint alleged, defendants represented that those products "were effective for their intended use" and "conformed with current good manufacturing practices," knowing that there was a "material risk" that the medicine "was not effective" and had been manufactured in substandard fashion.

The second claim alleged a violation of ORS 646.608(1)(b), which bars "[c]aus[ing] likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of \*\*\* goods." Specifically, the state alleged that defendants violated that prohibition by failing to disclose the material risk that the Motrin caplets sold in Oregon stores "were not manufactured consistent with current good manufacturing practices."

The third claim alleged violations of ORS 646.608(1)(g), which proscribes misrepresenting that goods are of a particular standard, quality, or grade. Defendants were alleged to have violated that provision by advertising, promoting, offering for sale, and selling Motrin 8-count vials and 24-count bottles in Oregon and failing to disclose "the material risk that the Motrin caplets contained therein were not manufactured consistent with current good manufacturing practices."

In its fourth claim, the state alleged a violation of ORS 646.607(1), barring unconscionable tactics in connection with the sale of goods. That claim, like the others, stemmed from the alleged failure to disclose the material risk of defect, information that "would have enabled Oregon consumers to make informed decisions when purchasing a medicine that was at material risk of being ineffective and seek restitution or replacement if appropriate."<sup>2</sup>

Defendants moved to dismiss the amended complaint, contending that the state's allegation of defendants' failure to disclose a "material risk" of product defect was insufficient to state a claim under the UTPA. Defendants' basic position—which was predicated upon their view of the "plain meaning" of the UTPA but also alluded to concepts of personal jurisdiction—was that a failure to disclose a material risk of product defect to Oregonians was not enough to establish an actionable "nexus" in Oregon unless it could be established that defective product was actually distributed in Oregon. That is, defendants posited, "the bad Motrin \*\*\* had to have made its way into Oregon" before the UTPA could be "triggered." Beyond that single, overarching premise that was asserted as being common to each of the state's four claims, defendants advanced no particularized challenges to the sufficiency of the state's individual claims with respect to the specific language of the various statutory clauses referenced by the complaint.

The state remonstrated that the complaint stated valid claims for relief, because the material risk that a product may be defective, regardless of whether it ultimately is proved to be defective, informs a rational consumer's assessment of products in a competitive market. Given the UTPA's remedial, consumer protection purposes, the state asserted, a manufacturer's failure to disclose a material risk that a drug it is selling in Oregon is defective is exactly the kind of deceptive business practice that the UTPA prohibits. During oral argument before the trial court, the state further noted

<sup>&</sup>lt;sup>2</sup> Our descriptions of the state's four claims are composite of the multiple counts within each claim, which separately allege violations relating to the sale of 8-count vials and 24-count bottles, and nondisclosure to consumers versus nondisclosure to retailers, among other things. Those distinctions are immaterial for purposes of our analysis.

To the extent that we refer to a "known" risk in the course of this opinion, we do so because that is what the state pleaded and argued. We express no opinion as to the potential liability under the UTPA of a defendant who fails to disclose a material risk of which the defendant did not have actual knowledge.

that—to the extent that defendants' position was premised on the absence of pleading that defective Motrin had actually been distributed and sold in Oregon—that circumstance was directly attributable to defendants' own highly irregular activities via the "secret shopper" campaign and failure to give prompt notice of the defective product.

The trial court, adopting defendants' framing of the UTPA, dismissed the state's action with prejudice, apparently in agreement with defendants' rationale. Although it did not explain its reasoning explicitly, based on the court's questions and commentary during the hearing, it evidently agreed with the defense that the state's claims were categorically precluded because the UTPA did not explicitly authorize claims involving misrepresentation of "material risk" of defect, and that, in order to properly state a claim, the state would have had to allege that the defective Motrin actually reached Oregon.

On appeal, the parties substantially reiterate their arguments. The state asserts that, as a textual matter, a known material risk that a specific product is defective is a "characteristic" or "quality" of the product that negatively affects its monetary value and commercial attractiveness, and, consequently, that misrepresenting such a risk is actionable. In that regard, the state emphasizes that, in *Caldwell*, we held that a seller's failure to disclose a material risk bearing on the value of a good (a mobile home) gave rise to an actionable UTPA claim. For their part, defendants counter that the text and legislative history of the UTPA, as well as decisions construing the UTPA, establish that the UTPA "prohibits only the misrepresentation of an actual fact \*\*\* that relates in some way to Oregon," and that a mere material risk that products sold in Oregon are defective does not qualify as such. In defendants' view, the UTPA encompasses only misrepresentations regarding "actual facts" that are completely certain and does not prohibit representations that are "merely at 'risk' of being untrue."

The trial court's conclusion and defendants' arguments in support of dismissal rest on the premise that a material risk of defect is, as a categorical matter, not a "fact" subject to the UTPA, and, thus, there was no actionable misrepresentation under the UTPA, as alleged in each of the state's four claims.

Thus framed, the central question presented to us—whether claims involving misrepresentation of a known material risk are actionable under the UTPA—is one of statutory interpretation. In construing the operative provisions, we adhere to our usual statutory construction methodology, as amplified in <u>State v. Gaines</u>, 346 Or 160, 206 P3d 1042 (2009), and our goal is to discern the legislature's intent.

Before addressing the operative provisions, we briefly highlight the UTPA's underlying policies and basic structure. The UTPA is a remedial statutory scheme, "enacted as a comprehensive statute for the protection of consumers from unlawful trade practices." Pearson v. Philip Morris, Inc., 358 Or 88, 115, \_\_\_ P3d \_\_\_ (2015); Raudebaugh v. Action Pest Control, Inc., 59 Or App 166, 171, 650 P2d 1006 (1982). As such, it is to be construed liberally to effectuate the legislature's intent, to the extent that a proposed construction is supported by the operative text. See Denson v. Ron Tonkin Gran Turismo, Inc., 279 Or 85, 90 n 4, 566 P2d 1177 (1977) (suggesting that the UTPA "is to be interpreted liberally as a protection to consumers" and businesses alike); Wolverton v. Stanwood, 278 Or 341, 345, 563 P2d 1203 (1977) (finding a "middle ground" between a "broad reading" of the UTPA's general policy and the inherent limits of the operative text; construing the requirement that actionable conduct occur "in the course of business" so as to apply "only to those unlawful practices which arise out of transactions which are at least indirectly connected with the ordinary and usual course of [a] defendant's business"). Thus, our inquiry is pervasively informed by the appreciation that the UTPA is a remedial statutory scheme that should, to the extent consonant with the Gaines construct, be construed so as to effectuate its consumer protection purposes.

Consistently with those purposes, the UTPA authorizes both public and private enforcement of its provisions. The state may investigate and bring actions to enjoin and penalize violations. Unlike a private litigant, who "may bring a UTPA claim only if it has suffered an 'ascertainable loss of money or property' as a result of a 'willful' violation of the statute, [those] requirements do not apply when the state brings a UTPA claim." <u>Rathgeber v. James Hemenway,</u> <u>Inc.</u>, 335 Or 404, 413 n 5, 69 P3d 710 (2003); see ORS 646.618 (authorizing investigations); ORS 646.632 (describing state UTPA enforcement processes); ORS 646.638(1) (setting out "ascertainable loss" requirement for private actions); ORS 646.642 (authorizing enforcement of injunctions and compliance agreements and civil penalties).

The UTPA authorizes action against a panoply of deceptive and unsafe business practices, including, among other things, misrepresentations made in connection with the sale of goods. *See Pearson*, 358 Or at 115 ("The trade practices declared unlawful under the UTPA are extensive, too much so for description."). Actionable representations under the UTPA "may be any manifestation of any assertion by words or conduct, including, but not limited to, a failure to disclose a fact." ORS 646.608(2); *see Pearson*, 358 Or at 115 (observing that misrepresentations can occur either by misstating a fact or by failing to disclose a fact).

The UTPA's "misrepresentation" provisions encompass a wide array of factual misrepresentations about the nature of a product, including, but not limited to, facts relating to its "source, sponsorship, approval, or certification," ORS 646.608(1)(b); "sponsorship, approval, characteristics, ingredients, uses, benefits, quantities or qualities," ORS 646.608(1)(e); and "standard, quality, or grade" or "style or model," ORS 646.608(1)(g).<sup>3</sup> Those terms encompass a multitude of facts about a product's inherent qualities, including facts that, though not specifically listed, nonetheless fall within one or several of the enumerated categories.

The sweep and scope of those provisions—both with respect to the form and content of misrepresentations manifests the legislature's intent to broadly prohibit misrepresentations materially bearing on consumer purchasing

<sup>&</sup>lt;sup>3</sup> Related provisions, not implicated here, prohibit misrepresentations about specific or narrower categories of facts such as facts as to identity and ownership, ORS 646.608(1)(a); "geographic origin," ORS 646.608(1)(d); and newness and originality, ORS 646.608(1)(f). More generically, a catch-all provision, ORS 646.608(1)(u), authorizes claims against persons who engage in "any other unfair or deceptive conduct in trade or commerce."

choices. A material risk that a product has a latent defect is exactly the kind of inherent feature of a product implicated under ORS 646.608(1) and (2). If a product is advertised and sold as effective for its intended use, notwithstanding a known risk that the product may not be fully effective, that risk itself is a "fact" for purposes of the UTPA, and its nondisclosure is actionable under the UTPA.<sup>4</sup>

That conclusion comports with our analysis and holding in *Caldwell*. There, the buyer of a mobile home brought a UTPA claim against the seller, Pop's Homes, alleging that it had misrepresented the status of the mobile home's location in a trailer park when the defendant seller had known of, but not disclosed, a risk that the mobile home could not remain there. 54 Or App at 106. The buyer had contacted the defendant, which was in the business of selling used mobile homes on consignment, with the express purpose of buying a mobile home already set up for occupancy in a trailer park near downtown Portland. The defendant, which had separate sales offices for "in-park" mobile homes (located in and set up for occupancy in parks) and "lot sales" (for mobile homes on the premises and without a space in a park), had directed the buyer to its in-park sales office. Id. at 107. After being shown two mobile homes in the same park, the buyer, interested in one of them, asked the defendant's sales representative why its owner was selling. The representative responded that the owner wanted a larger space. The defendant, although it had information

<sup>&</sup>lt;sup>4</sup> A hypothetical exemplifies this understanding. A multinational auto manufacturer, which distributes its vehicles for sale in Oregon, knows that a certain percentage of its vehicles have defective gas tanks whose weaknesses can produce lethal fires, but is uncertain whether any of those actually defective vehicles have been distributed in Oregon. The manufacturer does not disclose that risk (*viz.*, "One out of every 10,000 X-cars will blow up") in marketing its product in Oregon. Regardless of whether it could ever be established that any of the lethal cars had actually been sold in Oregon, would that risk, if disclosed, materially affect the purchasing choices of Oregon consumers, either by way of purchasing an alternative competing product or by paying less (perhaps much less) for an "X-car"? The answer is patent.

We acknowledge that the assessment and determination of materiality can, and will, vary in different circumstances, depending on the nature of the product and the likelihood and severity of the risk. However, here, we are not called upon to explore the contours of that matter, because defendants' position—and the trial court's ostensible concomitant rationale for dismissal—was categorical: *viz.*, nondisclosure of risk *qua* risk is not an actionable misrepresentation under the UTPA.

that the owner was selling because the trailer park "was being sold," did not disclose that information to the buyer.<sup>5</sup> *Id.* at 108. A month after moving in, the buyer learned that the property had been sold and would cease to operate as a trailer park, and that he had to vacate in 120 days. *Id.* 

The buyer sued the defendant under ORS 646.608(1)(e)and prevailed before a jury, but the trial court entered a judgment notwithstanding the verdict in favor of the defendant. *Id.* at 106. On appeal, we reversed, holding that the defendant's failure to disclose the change in ownership of the trailer park to the buyer constituted a false representation under the UTPA. We explained:

"In this case, defendant is charged with failing to tell plaintiff that the park was being sold. The testimony established that a mobile home's value would be substantially decreased if it had to be moved. The permanency of the location of the mobile home in the park was therefore both a 'characteristic' and a 'quality' of the home under ORS 646.608(1)(e). A change in ownership of the park obviously jeopardized an owner's ability to keep the mobile home \*\*\* *in situ*. Failure to communicate this fact constituted a false representation concerning a characteristic or quality of the mobile home. The trial court's ruling to the contrary was error."

### *Id.* at 110.

Thus, in *Caldwell*, we held that a seller's failure to disclose a known risk of some significant event or circumstance bearing materially on a buyer's purchasing decision is an actionable misrepresentation of a "characteristic" and "quality" under the UTPA. So too here. Just as in *Caldwell*, where the undisclosed risk that the mobile home might have to be relocated in the near future was a "characteristic" and "quality" whose nondisclosure was actionable, here, the undisclosed risk of product inefficacy—bearing materially on Oregon consumers' purchasing decisions (assuming, again, the truth of the allegations of the amended complaint)—constituted an actionable misrepresentation of "fact" for purposes of the UTPA.

<sup>&</sup>lt;sup>5</sup> It is unclear whether, at the time that representation was made to the plaintiff, the defendant was aware that the park was up for sale—and therefore at risk of being sold—or whether a sale was already pending. *See id.* at 108-10.

Defendants' effort to distinguish *Caldwell* is unavailing. Specifically, defendants assert that the actionable misrepresentation in that case was limited to the omission of the certain fact of the trailer park's impending sale, and did not encompass the corresponding risk concerning the mobile home's location. That argument ignores our fundamental characterization of the misrepresentation in *Caldwell*: "The permanency of the location of the mobile home in the park"—a feature that an impending change in ownership "obviously jeopardized." *Id*. In other words, the essential nondisclosure in *Caldwell* related to the then-existing *risk*, created by the park's pending sale, that the mobile home would have to be moved from the park—a risk bearing materially on the buyer's purchasing decision.

Defendants further contend that-regardless of Caldwell-Paul v. Providence Health System-Oregon, 351 Or 587, 273 P3d 106 (2012), establishes that claims predicated on a misrepresentation of a material risk of defect are not actionable under the UTPA. In Paul, the plaintiffs brought a private UTPA action after "computer disks and tapes containing records of 365,000 patients" were stolen from the defendant's employee's car. Id. at 589. The plaintiffs claimed that they were threatened with a loss of money due to the theft of their personal data and sought damages for funds expended to forestall those threatened losses. The Supreme Court concluded that the complaint failed to state a claim, holding that a private UTPA litigant's burden to allege "ascertainable loss of money or property" could not be satisfied by "such speculative losses as the *risk* of identity theft." Id. at 603 (emphasis in original). That holding, predicated exclusively and explicitly on a private UTPA litigant's burden to allege and prove "ascertainable loss," see ORS 646.638(1), is inapposite in the context of a UTPA enforcement action by the state. As noted, the "ascertainable loss" requirement does not apply to such actions. Rathgeber, 335 Or at 413 n 5.

Finally, we reject defendants' suggestion that, without an allegation (and consequent proof) that defective product was actually distributed in Oregon, no actionable conduct occurred in Oregon for purposes of triggering the UTPA. The actionable conduct was the failure to inform Oregonians of a known material risk that the Motrin they were purchasing might be defective. That conduct was legally sufficient to establish the requisite nexus under the UTPA.<sup>6</sup>

We end, as we began, with reference to the overarching consumer protective purposes of the UTPA and our obligation to construe its provisions, to the fullest extent consonant with *Gaines*, to effectuate those remedial purposes. The construction we adhere to today comports with *Caldwell* and effectuates the UTPA's remedial purposes. Conversely, defendants' construction would sanction calculated nondisclosure and manipulative suppression of information materially bearing on the purchasing choices of Oregon consumers.

The trial court erred in granting the motion to dismiss. That error, in turn, requires reversal of the court's award of attorney fees to defendants.

Reversed and remanded.

 $<sup>^{\</sup>rm 6}$  We reject without amplification defendants' remaining arguments, including their invocation of contextually inapposite statutes.