Filed 1/20/11 Certified for publication 2/9/11 (order attached)

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION FOUR

JOHNSON & JOHNSON, et al., Petitioners, v. THE SUPERIOR COURT OF LOS ANGELES COUNTY, Respondent; CHRISTOPHER TREJO, Real Party in Interest.	B226376 (Los Angeles County Super Ct. No. YC058023)

ORIGINAL PROCEEDINGS in mandate. William G. Willett, Judge. Petition denied.

Drinker Biddle & Reath, Thomas W. Pulliam, Jr., Vernon I. Zvoleff, Kenneth P. Conour, Benjamin J. Holl; O'Melveny & Myers, Charles C. Lifland and Amy J. Laurendeau for Petitioner.

No appearance for Respondent.

Law Offices of Brian D. Witzer, Inc., Rowena J. Dizon, Michael Manapol, Darren L. Schultz, Antonio R. Delgado and Brian D. Witzer for Real Party in Interest.

INTRODUCTION

In this action for negligence and strict products liability brought by plaintiff and real party in interest Christopher Trejo, petitioners Johnson & Johnson (J&J) and McNeil Consumer Healthcare Division (McNeil) challenge the trial court's July 30, 2010 amended order denying their motion for summary adjudication of issues regarding punitive damages. We issued an alternative writ of mandate and stayed the proceedings below. However, we now conclude that triable issues of material fact exist regarding whether the petitioners' actions surrounding their purported failure to provide adequate warnings on their ibuprofen product constituted malice, sufficient to support a claim for punitive damages. We therefore discharge the alternative writ, and deny the petition.

FACTUAL AND PROCEDURAL BACKGROUND

In October 2005, real party Trejo, then 15 years old, allegedly had a severe adverse reaction to Motrin, an over-the-counter (OTC) pain reliever containing ibuprofen (a non-steroidal anti-inflammatory drug (NSAID)), developing a rare and serious skin condition known as Stevens-Johnson Syndrome (SJS) and the more severe variant, Toxic Epidermal Necrolysis (TEN). McNeil is the manufacturer of OTC Motrin and an indirect subsidiary of J&J.

In 2008, Trejo sued petitioners for strict products liability, negligence, and breach of warranty. For strict liability, real party alleged that OTC Motrin contains

a design defect, that petitioners failed to provide adequate warnings concerning SJS and TEN (though they have long known about them), and that petitioners did not report and misrepresented study results to the FDA in obtaining its approval for OTC Motrin. In addition to damages for medical expenses, lost income, and lost earning capacity, real party seeks punitive damages on the strict liability claim for petitioners' alleged "despicable conduct . . . carried on by the defendant with a willful and conscious disregard of the rights or safety of others." (Civ. Code, § 3294, subd. (c)(1).)

The Motion for Summary Adjudication

In February 2010, petitioners moved for summary adjudication of the punitive damages claim on the ground real party lacks "clear and convincing proof" to support it. Real party opposed the motion for summary adjudication. On July 9, 2010, the trial court denied the motion, stating that real party "presented competent admissible evidence to show [petitioners] knew of the dangerous side effects of Ibuprofen, but did not apply to the FDA for additional warnings. Thus, [real party] presented competent admissible evidence to preclude the granting of the motion on the issue of punitive damages." The court cited the declarations submitted in opposition by real party's experts, Roger Salisbury and Randall Tackett, as containing evidence precluding summary adjudication.

The Writ Petition

The gist of petitioners' argument is that "McNeil has at all times marketed and sold Motrin with a label approved by the [FDA] and consistent with the FDA's standards for OTC medications." More specifically, petitioners assert as a factual matter that: "Since OTC Motrin's initial approval, the FDA has continued to

comprehensively regulate the product and its labeling. Any labeling changes made after initial approval must be approved by the FDA, which usually requires submission of a supplemental [New Drug Application (NDA)] with pharmacological, toxicological and clinical studies. Petitioners have complied with the FDA regulations and labeling requirements, and have had numerous communications with the FDA regarding the content of the OTC label." (Record citations omitted.) In summary, petitioners assert that "The FDA received comprehensive information about Motrin, including pharmacological, toxicological and clinical studies, and concluded on several occasions that the product is 'safe and effective for use as recommended' in the label. Regardless of whether Petitioners could or should have said something more explicit about SJS and TEN in the Motrin label, and regardless of whether different labeling would have made a difference to Plaintiff, McNeil's FDA-approved labeling cannot conceivably evidence despicable conduct or a conscious disregard for safety."

DISCUSSION

Petitioners' arguments are not entirely accurate in characterizing the relationship between and respective duties of the FDA and drug manufacturers. Given a full view of the nature of the relationship and respective duties, and the evidence presented, there is a triable issue of material fact whether petitioners' failure to provide adequate warnings of SJS and TEN constitutes malice so as to justify punitive damages.

I. The Relevant Law

A. *The Standard of Review*

"'An order denying a motion for summary adjudication may be reviewed by way of a petition for writ of mandate. [Citation.] Where the trial court's denial of a motion for summary judgment will result in trial on nonactionable claims, a writ of mandate will issue. [Citations.] Likewise, a writ of mandate may issue to prevent trial of nonactionable claims after the erroneous denial of a motion for summary adjudication. [¶] Since a motion for summary judgment or summary adjudication "involves pure matters of law," we review a ruling on the motion de novo to determine whether the moving and opposing papers show a triable issue of material fact. [Citations.]'" (*Arnall v. Superior Court* (2010) 190 Cal.App.4th 360, 364.)

"[F]rom commencement to conclusion, the party moving for summary judgment [or summary adjudication] bears the burden of persuasion that there is no triable issue of material fact and that he is entitled to judgment as a matter of law. . . . There is a triable issue of material fact if, and only if, the evidence would allow a reasonable trier of fact to find the underlying fact in favor of the party opposing the motion in accordance with the applicable standard of proof." (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 850.)

"In the usual case, the question of whether the defendant's conduct will support an award of punitive damages is for the trier of fact, 'since the degree of punishment depends on the peculiar circumstances of each case.' [Citations.] [¶] But the issue may be resolved on summary judgment, giving due regard to the higher proof standard. While 'the "clear and convincing" evidentiary standard is a stringent one, it does not impose on a plaintiff the obligation to "prove" a case for punitive damages at summary judgment.' (*American Airlines, Inc. v. Sheppard,*

Mullin, Richter & Hampton [(2002)] 96 Cal.App.4th [1017] at p. 1049.) 'However, where the plaintiff's ultimate burden of proof will be by clear and convincing evidence, the higher standard of proof must be taken into account in ruling on a motion for summary judgment or summary adjudication, since if a plaintiff is to prevail on a claim for punitive damages, it will be necessary that the evidence presented meet the higher evidentiary standard.' (*Ibid.*; [citations].) . . . [S]ummary judgment 'on the issue of punitive damages is proper' only 'when no reasonable jury could find the plaintiff's evidence to be clear and convincing proof of malice, fraud or oppression.' (*Hoch v. Allied-Signal, Inc.*, [(1994) 24 Cal.App.4th 48] at pp. 60-61.)" (*Spinks v. Equity Residential Briarwood Apartments* (2009) 171 Cal.App.4th 1004, 1053.) In reviewing the trial court' s denial of petitioners' motion for summary adjudication, we view the evidence with the higher burden of proof in mind.

B. *Federal Regulation of Drug Labeling*

As stated in Tackett's declaration submitted in opposition to the motion for summary adjudication: "In order to alert prescribers to new warnings as soon as possible, the FDA also permits manufacturers to add new warnings to their labeling without first securing FDA approval pursuant to 21 CFR 314.70."

In *Wyeth v. Levine* (2009) 129 S.Ct. 1187, the United States Supreme Court discussed this regulation: "Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this 'changes being effected' (CBE) regulation provides that if a manufacturer is changing a label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' or

to 'add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,' it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval. §§ 314.70(c)(6)(iii)(A), (C)." (*Wyeth v. Levine, supra*, 129 S.Ct. at p. 1196.)

"[T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that *the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market*. See, *e.g.*, 21 CFR § 201.80(e) (requiring a manufacturer to revise its label 'to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug'); § 314.80(b) (placing responsibility for postmarketing surveillance on the manufacturer); 73 Fed.Reg. 49605 ('Manufacturers continue to have a responsibility under Federal law . . . to maintain their labeling and update the labeling with new safety information')." (*Wyeth v. Levine, supra,* 129 S.Ct. at pp. 1197-1198, italics added.)

"Of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications. But absent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements." (*Id.* at p. 1198.)

In that case, "Wyeth [had contended] that the FDCA establishes both a floor and a ceiling for drug regulation: Once the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate, regardless of whether there is

any evidence that the FDA has considered the stronger warning at issue. The most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary. Building on its 1906 Act, Congress enacted the FDCA to bolster consumer protection against harmful products. [Citations.] Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." (*Id.* at pp. 1199-1200, fn. omitted.)

With that legal framework in mind, we will next discuss the relevant factual circumstances which lead us to conclude that triable issues of material fact exist based upon which a reasonable jury could conclude by clear and convincing evidence that petitioners were guilty of "despicable conduct . . . carried on by the defendant with a willful and conscious disregard of the rights or safety of others." (Civ. Code, § 3294, subd. (c)(1).)

II. The Relevant Facts

In 1974, prescription Motrin (then manufactured by Upjohn Mfg. Co.) was first approved by the FDA via the new drug application process. Labeling for prescription ibuprofen has always contained references to SJS, TEN, and "life-threatening" reactions; thus, the FDA has long been aware of the alleged causal connection between ibuprofen and SJS/TEN.

In 1984, the FDA approved Upjohn's new drug application for *OTC* adult ibuprofen "is safe and effective for use as recommended in the submitted labeling." The formula, but not the dosage, of the OTC product is the same as the prescription

product. The *OTC* labeling has never made specific reference to SJS/TEN by name.

In 1994, the FDA approved a new drug application from McNeil for ibuprofen in the form of gelcaps, again finding the drug "safe and effective for use as recommended in the submitted labeling."

The OTC Motrin label approved by the FDA in October 2000 and on the box of the Motrin that real party took contained this warning:

"**WARNINGS:**

Allergy Alert: Ibuprofen may cause a severe allergic reaction which may include:

■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.

Stop use and ask a doctor if

■ an allergic reaction occurs. Seek medical help right away

■ pain gets worse or lasts more than 10 days

■ fever gets worse or lasts more than 3 days

■ stomach pain or upset gets worse or lasts

■ redness or swelling is present in the painful area

■ any new symptoms appear"

Following a February 2005 joint meeting of the FDA's Arthritis and Drug Safety and Risk Management Advisory Committees, the FDA (in June 2005) required labeling changes to all non-prescription NSAID products, including ibuprofen. One change required that the "Allergy alert" for those products be "revised to include . . . a description of early symptoms associated with [SJS]."

Specifically, the FDA required these symptoms be added to the allergy portion of the warning: skin reddening, rash, and blisters. McNeil implemented the changes within the six months required by the FDA.

The box of Motrin plaintiff used in October 2005 contained the warnings approved for the time period 2000 to 2005. The newest warnings were not required to be implemented until December 2005.

In February 2005, plaintiff's experts Salisbury and Tackett, among others, signed a "Citizen Petition to Request Risk Assessment of the Risks from SJS and TEN associated with ibuprofen." The petition requested an investigation into the alleged withholding of critical safety information by McNeil, withdrawal of FDA approval for OTC ibuprofen products including Motrin, or the addition of specific warnings for "life-threatening reactions," "SJS" and "TEN."

In its response, the FDA declined to remove ibuprofen products from the marketplace or to further alter the label. The FDA noted its 2005 comprehensive review of the risks and benefits, including the risks of SJS and TEN, of all approved NSAID products, including ibuprofen. The FDA noted that it had already requested that manufacturers make labeling changes: "[W]e have requested that manufacturers include under the *Allergy alert* subheading the symptoms associated specifically with SJS and TEN. We do not believe that it is useful to include the specific terms *SJS, TEN* . . . in the OTC label because most consumers are unfamiliar with these terms. In addition, effective OTC labeling communicates warning information in a manner that consumers can quickly and easily identify and understand. Consequently, we believe a description of symptoms is more appropriate."

The FDA also noted that there was no evidence provided by the citizen petition to support its claim that McNeil or other manufacturers had withheld safety information from the FDA.

III. Triable Issues of Material Fact Remain

Real parties have made a showing that: (1) as the manufacturer, McNeil (not the FDA) was responsible for crafting a label with adequate warnings, and was empowered by FDA regulations to warn of the risks of SJS/TEN without prior approval by the FDA (*Wyeth, supra*); (2) the FDA itself ultimately required a warning of the early symptoms of SJS/TEN; (3) long before this FDA ruling, McNeil knew that SJS/TEN could cause severe harm and knew of the alleged connection between SJS/TEN and Motrin, but did not exercise its power to modify the label to warn of the risks or symptoms of SJS/TEN (a warning that, inferably, the FDA would have approved, given its later ruling requiring a description of the symptoms of SJS/TEN). Drawing all inferences in favor of real party as is required on summary adjudication, while bearing in mind that the plaintiff's evidence must be such as would allow a reasonable trier of fact to find in plaintiff's favor by clear and convincing evidence, we conclude that the evidence raises a triable issue whether McNeil failed to warn of SJS/TEN in its labeling, with conscious disregard of the risk to safety from those conditions.

A. *Petitioners Had Long Been Aware of the Risk of SJS/TEN Associated with Ibuprofen*

Real party has demonstrated that McNeil has known since the 1980s that ibuprofen is associated with SJS/TEN, yet never asked the FDA to include that fact in the OTC label warning, despite the fact it could have done so. Foreign labels for

Motrin have long contained more information about SJS/TEN than United States labels, e.g., a patient information leaflet inside bottles of OTC Motrin sold in Germany warns "of the side effects associated with this OTC product of rare but serious skin reactions, such as reddening and blister formation . . . which is bullous EM/SJS." As Tackett stated in his declaration, the information was appearing in foreign warnings in 2005 and before, and had petitioners applied to the FDA for additional warnings, the additional warnings ultimately required by the FDA in 2005 (skin reddening, rash, and blisters) likely would have been required by the FDA prior to 2005, before real party's mother purchased the Motrin, and prior to real party ingesting the Motrin.

Based on the FDA's response to the citizen petition, petitioners assert that "we now know that even if Petitioners had asked to change the OTC Motrin label to contain a more explicit warning about SJS and TEN, the FDA would have rejected any reference to SJS and TEN *by name* 'because most consumers are unfamiliar with these terms.' The FDA might have permitted McNeil to add some of the early SJS and TEN symptoms (including skin reddening, rash and blisters) to the allergy warning on the label, *since it eventually approved that addition after a comprehensive review of all NSAIDs.*" (Italics added; record citations omitted.) But real party's position is not that petitioners should have referred by name to SJS/TEN on the label; rather, he asserts that petitioners should have acted earlier to change the labeling to identify symptoms related to SJS/TEN.

In fact, the FDA's response to the citizen petition supports real party's position. While the FDA stated that it would not require OTC ibuprofen products to refer to SJS/TEN by name, or to refer to "life-threatening" skin reactions, this was not a rejection of the citizen's petition's essential point that OTC ibuprofen needed to warn consumers about SJS/TEN. In fact, it was only because the FDA

had *already* instructed manufacturers of ibuprofen to warn consumers about the symptoms of SJS/TEN, that one could even characterize the FDA's response to the citizen petition as a rejection. Instead, the FDA's response shows that when it finally did focus specifically on the issue of OTC labeling regarding warnings about SJS/TEN, *it concluded that warnings were needed.* The warning was not to refer to the condition by name because that would not help consumers; consumers instead needed to be warned about specific symptoms associated with this very serious adverse reaction: ("skin reddening, rash, and blisters"). Real party's point is that petitioners knew of the risk, and showed conscious disregard for safety by waiting for the FDA to require labeling changes, rather than making those changes on their own and then seeking approval. As discussed above, federal regulations permit labeling changes without FDA approval to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." That being the case, and given all of the circumstances involved here, there are triable issues of fact regarding whether McNeil's FDA-approved labeling could evidence despicable conduct or conscious disregard for safety. The relevant federal regulations place the burden on manufacturers to ensure their drug labeling is adequate at all times, regardless of FDA approval of existing labeling.

We note that petitioners give the impression that they have been in discussions and having frequent contact with the FDA about labeling of the OTC ibuprofen products on a continuous basis. They point to an occasion on which they proposed changes to the OTC label to add additional safety warnings, which were not approved, and the FDA indicated the labeling change would result in the product being "misbranded." But this information is irrelevant, because the

proposed change had to do with dosing (having nothing to do with SJS/TEN or its symptoms), and the FDA's point was that adding a dosage warning as McNeil proposed would render the prescription dosing information problematic (the prescription and OTC forms differ only in their dosage, not in formula).

B. *The Change in Labeling Is Significant for Purposes of Deciding the Motion for Summary Adjudication*

Petitioners argue that, in any event, "the difference between a label that warns of the risk of a severe allergic reaction and instructs users who develop an allergic reaction to stop taking Motrin and seek medical help right away, and one that warns of severe allergic reaction that may include skin reddening, blisters and rash, surely does not evince conscious disregard of safety or despicable conduct, let alone clear and convincing evidence of conscious disregard or despicable conduct." On the contrary, we conclude that there is arguably a significant difference between a general warning of "allergic reaction" versus a description of the specific symptoms associated with the rare but potentially fatal conditions at issue here. We are not prepared to decide as a matter of law that the difference in labeling was unimportant, or that real party's injury would still have occurred had the labeling been changed. The focus of the petition is not causation—whether the failure to warn was a substantial factor in bringing about real party's injury—but solely whether the failure to warn is sufficient to show malice so as to support punitive damages.

C. *The Purported Withholding of Information from the FDA*

In further support of his claim for punitive damages, real party also contends that petitioners withheld scientific information from the FDA, although he

concedes that all of the information was provided to the FDA as part of the citizen petition. In response to the citizen petition, the FDA stated that it had no evidence that petitioners had withheld any relevant information. For purposes of the present writ petition, real party argues in essence that the information was buried in voluminous data submitted to the FDA, when it instead should have been highlighted. Suffice it to say that we conclude triable issues of fact remain as to whether petitioners' provision of the information was done in a manner that would sufficiently call it to the FDA's attention, particularly given the severity of the harm which can result from SJS/TEN.

D. *Petitioners' Request for Judicial Notice Is Denied*

Finally, we deny petitioners' request that we take judicial notice of other, unrelated Motrin cases in California involving punitive damage claims. While we may take judicial notice of the *existence* of judicial opinions, court documents, and verdicts reached, we cannot take judicial notice of the truth of hearsay statements in other decisions or court files (see *Williams v. Wraxall* (1995) 33 Cal.App.4th 120, 130, fn. 7), or of the truth of factual findings made in another action. (*Fowler v. Howell* (1996) 42 Cal.App.4th 1746, 1749; *Sosinsky v. Grant* (1992) 6 Cal.App.4th 1548, 1568-1569.) Thus, the rulings of other courts in purportedly similar matters are not relevant or helpful to our de novo review of the trial court's ruling on a motion for summary adjudication. (See *Deveny v. Entropin, Inc.* (2006) 139 Cal.App.4th 408, 418.)

DISPOSITION

The petition for writ of mandate or other extraordinary relief is denied. The alternative writ, having served its purpose, is discharged, and the temporary stay order is lifted upon finality of this decision. Real party in interest shall have his costs.

WILLHITE, J.

We concur:

EPSTEIN, P. J.

SUZUKAWA, J.

Filed 2/9/11 Order Granting Publication

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CHRISTOPHER TREJO,

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B226376

(Los Angeles County Super Ct. No. YC058023)

ORDER CERTIFYING OPINION FOR PUBLICATION

THE COURT:*

Good cause appearing, it is ordered that the opinion in the above entitled matter, filed January 20, 2011, be published in the official reports.

*EPSTEIN, P. J. WILLHITE, J. SUZUKAWA, J.