

Filed 2/7/13

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION FIVE

POMONA VALLEY HOSPITAL
MEDICAL CENTER,

Petitioner,

v.

THE SUPERIOR COURT OF LOS
ANGELES COUNTY,

Respondent;

APRIL CHRISTINE CABANA,

Real Party in Interest.

No. B245224

(L.A. Super. Ct. No. BC465313)

ORIGINAL PROCEEDINGS; petition for writ of mandate. Michael P. Linfield,
Judge. Writ granted.

Lewis, Brisbois, Bisgaard & Smith, Judith M. Tishkoff and L. Susan Snipes for
Petitioner.

Baum, Hedlund, Aristei & Goldman, Ronald L.M. Goldman, Bijan Esfandiari and
A. Ilyas Akbari for Real Party in Interest.

No appearance for Respondent.

Code of Civil Procedure section 425.13, subdivision (a),¹ as interpreted in *College Hospital Inc. v. Superior Court* (1994) 8 Cal.4th 704 (*College Hospital*), precludes a plaintiff from alleging punitive damages against a health care provider unless the plaintiff demonstrates “a substantial probability” that she will “prevail on the claim.” Based on a declaration from counsel for plaintiff and real party in interest April Christine Cabana and three letters obtained from a third party defendant, respondent court granted plaintiff’s motion to amend her complaint to allege a claim for punitive damages against petitioner and defendant Pomona Valley Hospital and Medical Center (the Hospital).

We issued an alternative writ of mandate to respondent court, citing, inter alia, *College Hospital*, which rejected an attempt to amend a complaint to allege punitive damages based on a showing far stronger than plaintiff’s. Our alternative writ directed respondent court to reconsider and reverse its ruling, or show cause before this court why a peremptory writ should not issue directing it to do so. Respondent court held a hearing in compliance with the alternative writ but concluded it had properly granted the motion to amend the complaint to allege punitive damages.

Because plaintiff’s counsel’s declaration and the three letters are insufficient as a matter of law to support the motion to amend the complaint to allege punitive damages, we direct respondent court to set aside its order and enter a new order denying the motion.

¹ Further statutory references are to the Code of Civil Procedure unless otherwise stated.

BACKGROUND

Plaintiff's Complaint

Plaintiff filed a complaint on July 13, 2011, against various defendants, including the Hospital². Defendant Dr. Ali H. Mesiwala performed surgery at the Hospital on plaintiff for back pain on September 26, 2008, using two products manufactured by defendant Stryker Biotech, LLC—Calstrux and OP-1. Plaintiff alleged the mixture had not been approved by the Food and Drug Administration. Complications from use of the products in the surgery resulted in injury requiring a second surgery. The Hospital was named as a defendant only in the eleventh cause of action, which alleged negligence by the Hospital staff in connection with the two surgeries.

Plaintiff's Motion to Amend the Complaint and Seek Punitive Damages

On August 20, 2012, plaintiff filed a motion to amend her complaint against the Hospital to allege three new causes of action: (1) violation of Health and Safety Code section 24170 et seq. (the Protection of Human Subjects in Medical Experimentation Act); (2) fraud; and (3) negligence per se. In addition, plaintiff moved for leave to amend to seek punitive damages against the Hospital in the manner required by section 425.13.

The sworn evidence presented in support of the motion to amend consisted of a declaration from plaintiff's counsel and three attached letters from the Hospital's Institutional Review Board (IRB)³ to Dr. Mesiwala. Plaintiff's counsel declared that

² The Hospital was named as a defendant by amendment on October 11, 2011, after plaintiff complied with the notice requirements of section 364.

³ "An IRB is 'any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to

defendant Stryker Biotech had provided discovery of approximately 85,000 pages of documents, including the three letters. Counsel described the three letters as showing the Hospital “was conducting a secret ‘research project’ which included patient ‘randomization’ to test the experimental/humanitarian device OP-1 Putty on patients at the hospital.” Counsel asserted the letters demonstrated plaintiff was an unwitting participant in a secret research project conducted by the Hospital. The balance of counsel’s declaration consisted of argument as to why the proposed amendments should be allowed.

The three letters relied upon by plaintiff were on the Hospital’s letterhead, addressed to Dr. Mesiwala. Each letter pertained to “Protocol Study: OP-1 Putty: An FDA approved device under the Humanitarian Use Device (HUD) regulations.” The letters were signed by either the chairperson or vice-chair of the Hospital’s IRB.

The first letter, dated February 4, 2009, gave approval of “your request” for annual renewal by the IRB of the OP-1 Putty protocol study. The letter indicated that information submitted in connection with the annual renewal showed four subjects in the study, all of whom were “still alive” and “in follow-up.” “While the PVHMC Board has approved the study, we are requesting the following information be submitted as soon as possible in order to better understand your study: 1. How many patients are enrolled nationally? 2. You mentioned that the material and procedure under study are very effective. If efficacy is obvious, should the research project and randomization be continued? Is there an ongoing statistical review process to make sure that the incoming study data do not indicate that the study should be terminated?” Dr. Mesiwala was directed to immediately report any ill effects on patients to the IRB. Approval of the protocol would expire on January 27, 2010.

assure the protection of the rights and welfare of the human subjects.’ (21 C.F.R. § 56.102(g) (2012).) An IRB is also referred to under federal law as an ‘institutional review committee.’ (*Ibid.*, italics omitted.)” (*Pomona Valley Hospital Medical Center v. Superior Court* (2012) 209 Cal.App.4th 687, 690.)

The second letter from the IRB to Dr. Mesiwala was dated February 4, 2010. This letter also related to “your request” for annual renewal of the OP-1 Putty protocol study. Information submitted showed 17 subjects, all of whom were still alive and in follow-up. The renewal was for ten months, and Dr. Mesiwala was again directed to immediately notify the IRB of any unexpected ill effects on patients.

The final letter to Dr. Mesiwala was dated January 25, 2012. The IRB approved closing the study “since patients are beyond normal follow-up care.” The letter asked what Dr. Mesiwala considered to be normal follow-up, when the last follow-up was done, and how “are the other patients doing generally?” Dr. Mesiwala was directed to submit “this paperwork” to the IRB coordinator.

The proposed amended complaint sought to add causes of action 12-14 against the Hospital. The 12th and 13th causes of action sought punitive damages based on the Hospital’s malicious, fraudulent, and oppressive conduct toward plaintiff and alleged plaintiff was unaware she was one of at least 17 patients enrolled in a five-year research project to which she never consented. The 12th cause of action alleged violation of Health and Safety Code section 24170, the Protection of Human Subjects in Medical Experimentation Act, by approving a research project which “randomized patients” to test the safety and efficacy of OP-1 Putty on patients. The 13th cause of action for fraud alleged the Hospital concealed plaintiff’s participation in the OP-1 Putty research project.

The Hospital’s Opposition to the Motion to Amend

The Hospital argued the motion to amend was untimely. It also filed evidentiary objections to the declaration of plaintiff’s counsel and to the three attached documents. On the merits, the Hospital opposed the motion to amend to allege punitive damages on several grounds, including that plaintiff failed to demonstrate a substantial probability of prevailing on the punitive damages claims as required by section 425.13. The Hospital argued that plaintiff had “not presented one scintilla of competent evidence to show that

she is entitled to punitive damages” and “[t]here are no facts presented to establish a ‘secret research project.’ There is no evidence of [the Hospital’s] role in such a project.”

Plaintiff’s Reply to the Opposition

Plaintiff argued she had substantiated that she was enrolled as an unwitting test subject in the Hospital’s OP-1 Putty research project. The Hospital is subject to punitive damages for engaging in conduct that constitutes conscious disregard of the rights or safety of others by enrolling plaintiff in nonconsensual human experimentation.

Respondent Court’s Ruling

On September 12, 2012, respondent court overruled the Hospital’s evidentiary objections, found the motion to amend timely, and granted the motion to amend the complaint to add the 12th-14th causes of action, with punitive damage allegations as to the 12th and 13th causes of action.⁴ Specifically addressing the Hospital’s argument that there was insufficient evidence to support a claim for punitive damages, respondent court ruled the copies of the IRB correspondence provided to plaintiff by Stryker Biotech “is sufficient.”

DISCUSSION

The Hospital filed the instant petition arguing, in part, that plaintiff failed to meet her burden of showing a substantial probability of prevailing on a claim of punitive damages under section 425.13. The Hospital contends the three letters from the IRB to Dr. Mesiwala at most establish there was a research project, but plaintiff did not submit

⁴ Because we resolve the issue on the merits, we do not address the evidentiary objections or timeliness issues.

any competent evidence the project was secret, that she was enrolled in the project, or that its existence was concealed from her. In addition, nothing in the documents show any misrepresentation by the Hospital, any intent to deceive plaintiff, or reliance. The letters do not establish any evidence of malice or oppression by the Hospital.

Plaintiff's return to the petition for writ of mandate⁵ argues the February 4, 2009 letter to Dr. Mesiwala establishes plaintiff's initial surgery was part of a research project and statistical review of study data involving OP-1 Putty. The second letter, dated February 4, 2010, confirmed a total of 17 "subjects." The third letter, dated January 25, 2012, informed Dr. Mesiwala the committee approved closing the study to "patient accrual" and inquired as to "[h]ow are the other patients doing generally?" The Hospital's IRB had a duty to obtain consent from plaintiff for use of the experimental putty in her surgery. Based on the three letters, plaintiff argued that respondent court properly ruled plaintiff had substantiated a claim for punitive damages.

Standard of Review

A trial court's ruling on a motion to amend a complaint to allege punitive damages is subject to the de novo standard of review. (*College Hospital, supra*, 8 Cal.4th at pp. 719, fn. 6, 772-773.) "[A] motion to amend the complaint to state a punitive damages claim under section 425.13(a) must be granted unless, after reviewing the supporting and opposing materials, the court concludes that the allegations made or the evidence adduced in support of the claim, even if credited, are insufficient as a matter of law to support a judgment for punitive damages." (*Id.* at p. 719, fn. 6.)

⁵ Plaintiff attached to its return a partial transcript of Dr. Mesiwala's December 13, 2012 deposition testimony. We shall not consider deposition testimony taking place three months after respondent court granted the motion to amend the complaint. Writ review does not provide for consideration of evidence not before respondent court at the time of its ruling. (*Guardado v. Superior Court* (2008) 163 Cal.App.4th 91, 95, fn. 1; *BGJ Associates v. Superior Court* (1999) 75 Cal.App.4th 952, 957-958.)

Section 425.13

Section 425.13, subdivision (a)⁶ “bars inclusion of a punitive damages claim in certain actions against health care providers unless the plaintiff first demonstrates a ‘substantial probability’ that he ‘will prevail’ on the claim.” (*College Hospital, supra*, 8 Cal.4th at p. 709.) As in *College Hospital*, “there is no dispute that the punitive damages claim ‘directly relates’ to services rendered by the Hospital, a health care provider. Our task is to determine the type of pleading hurdle presented, and whether its requirements have been met in this case.” (*Id.* at p. 714.)

“[T]he gravamen of section 425.13[, subdivision] (a) is that the plaintiff may not amend the complaint to include a punitive damages claim unless he both states and substantiates a legally sufficient claim. In other words, the court must deny the section 425.13[, subdivision] (a) motion where the facts asserted in the proposed amended complaint are legally insufficient to support a punitive damages claim. (See §§ 430.10, 436–437.) The court also must deny the motion where the evidence provided in the ‘supporting and opposing affidavits’ either negates or fails to reveal the actual existence of a triable claim. (See § 437c, subd. (c).) The section 425.13[, subdivision] (a) motion may be granted only where the plaintiff demonstrates that both requirements are met.” (*College Hospital, supra*, 8 Cal.4th at p. 719, fn. omitted.) The plaintiff may

⁶ Section 425.13, subdivision (a) provides as follows: “In any action for damages arising out of the professional negligence of a health care provider, no claim for punitive damages shall be included in a complaint or other pleading unless the court enters an order allowing an amended pleading that includes a claim for punitive damages to be filed. The court may allow the filing of an amended pleading claiming punitive damages on a motion by the party seeking the amended pleading and on the basis of the supporting and opposing affidavits presented that the plaintiff has established that there is a substantial probability that the plaintiff will prevail on the claim pursuant to Section 3294 of the Civil Code. The court shall not grant a motion allowing the filing of an amended pleading that includes a claim for punitive damages if the motion for such an order is not filed within two years after the complaint or initial pleading is filed or not less than nine months before the date the matter is first set for trial, whichever is earlier.”

not rely on allegations of its own pleadings, even if verified, to satisfy the required evidentiary showing. (*Id.* at p. 720, fn. 7.)

“[S]ection 425.13[, subdivision] (a) does not contemplate a minitrial in which witness testimony is introduced. As we have seen, a section 425.13[, subdivision] (a) motion, like a motion for summary judgment, is decided entirely on an ‘affidavit’ showing.” (*College Hospital Inc., supra*, 8 Cal.4th at p. 717.) The trial courts are not authorized to weigh the merits of the claim or consider its likely outcome at trial. “Rather than requiring the *defendant* to defeat the plaintiff’s pleading by showing it is legally or factually meritless, the motion requires the *plaintiff* to demonstrate that he possesses a legally sufficient claim which is ‘substantiated,’ that is, supported by competent, admissible evidence.” (*Id.* at p. 719.)

“[S]ubstantiation of a proposed punitive damages claim occurs only where the factual recitals are made under penalty of perjury and set forth competent admissible evidence within the personal knowledge of the declarant. (See §§ 437c, subds. (b) & (d), 2015.5.) Consistent with the legislative intent to protect health care defendants from the drastic effects of unwarranted punitive damage claims, the entire package of materials submitted in support of the section 425.13[, subdivision] (a) motion should be carefully reviewed to ensure that a genuine contestable claim is indeed proposed.” (*College Hospital, supra*, at pp. 719-720, fn. omitted.)

Analysis of the Sufficiency of Plaintiff’s Showing

The premise of plaintiff’s punitive damages claim is that the letters from the IRB to Dr. Mesiwala demonstrate the Hospital was conducting a secret research project, plaintiff was unwittingly enrolled in the project, and plaintiff would not have consented to participation. Plaintiff’s showing in support of the motion to amend the complaint contains no competent evidence to substantiate any of these claims

We begin by reiterating that the burden was on plaintiff to substantiate her claim for punitive damages with “factual recitals” which were “made under penalty of perjury”

and “set forth competent admissible evidence within the personal knowledge of the declarant.” (*College Hospital, supra*, 8 Cal.4th at pp. 719-720.) *College Hospital* made clear that plaintiff’s own pleading is entitled to no evidentiary weight in the analysis. (*Id.* at p. 720, fn. 7.)

The only sworn evidence before respondent court was the declaration by plaintiff’s counsel. Counsel’s declaration established personal knowledge of only one fact relevant to the issue of punitive damages—that the three letters on Hospital letterhead were a part of the discovery received from Stryker Biotech. Counsel set forth no personal knowledge of the existence of a secret research study conducted by the Hospital, plaintiff’s participation in the study, or her lack of consent.

Setting aside the facial inadequacy of counsel’s declaration, the three letters relied upon by plaintiff and respondent court do not establish that the Hospital was conducting a secret research project, that plaintiff was a subject of such a project, or that if a project existed, she did not consent to participation. The letters reflect that protocol study of OP-1 Putty was conducted by Dr. Mesiwala. The February 2009 and February 2010 letters are addressed to Dr. Mesiwala and refer explicitly to “*your request* for annual renewal” (emphasis added) of the OP-1 Putty protocol study.

The February 2009 letter asks Dr. Mesiwala to submit information “as soon as possible in order to better understand *your study* (emphasis added),” regarding the number of patients “enrolled nationally,” whether “randomization” should be continued if the procedure is effective, and if there is statistical evidence pertaining to the study. The 2009 and 2010 letters direct Dr. Mesiwala to immediately communicate if there are any “unexpected ill effects on the patient(s) as a result of this study.”

Nothing in the letters from the IRB to Stryker Biotech show that the Hospital, as opposed to Dr. Mesiwala, was conducting a study. The letters do not reflect the existence of a secret research project—the word secret is nowhere found in any of the letters. Because the participants in the protocol are not identified in the letters, they provide no proof that plaintiff was part of a study, or that if she were, she did not give informed consent to Dr. Mesiwala.

For these same reasons, respondent court erred in finding that plaintiff had demonstrated malice on the part of the Hospital through competent evidence. Civil Code section 3294, subdivision (a)⁷ requires “clear and convincing” proof of “oppression, fraud, or malice” to warrant punitive damages in an action not based on contract. As defined in Civil Code section 3294, subdivision (c),⁸ “the punishable acts which fall into these categories are strictly defined. Each involves ‘intentional,’ ‘willful,’ or ‘conscious wrongdoing’ of a ‘despicable’ or ‘injur[ious] nature. [Citation.]” (*College Hospital, supra*, 8 Cal.4th at p. 721.) Plaintiff relies on the theory that the Hospital acted with conscious disregard for her safety.

Plaintiff’s counsel’s declaration is not based on any personal knowledge of conduct by the hospital regarding plaintiff, so it necessarily does not amount to clear and convincing proof of the elements of malice. The letters relied on by plaintiff also fail, as a matter of law, to show malice. Nothing in the letters suggests the Hospital engaged in, or was complicit in, a secret study conducted without knowledge of the participants. The IRB letters to Dr. Mesiwala make no reference of any kind to plaintiff. They show nothing more than the IRB’s performance of its official function in connection with Dr. Mesiwala’s study of OP-1 Putty. The letters reflect the IRB’s consideration of the submissions by Dr. Mesiwala, questions the IRB directed to Dr. Mesiwala, and directions

⁷ Civil Code section 3294, subdivision (a) provides as follows: “In an action for the breach of an obligation not arising from contract, where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice, the plaintiff, in addition to the actual damages, may recover damages for the sake of example and by way of punishing the defendant.”

⁸ Civil Code section 3294, subdivision (c) provides as follows: “(1) ‘Malice’ means conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others. [¶] (2) ‘Oppression’ means despicable conduct that subjects a person to cruel and unjust hardship in conscious disregard of that person’s rights. [¶] (3) ‘Fraud’ means an intentional misrepresentation, deceit, or concealment of a material fact known to the defendant with the intention on the part of the defendant of thereby depriving a person of property or legal rights or otherwise causing injury.”

to him to immediately report any unexpected adverse results. The IRB's conduct, as reflected in the letters, lacks any hint of the necessary element of "despicable conduct" required for malice on the theory of "conscious disregard of the rights and safety of others." (See *College Hospital, supra*, 8 Cal.4th at p. 725 [malice based on conscious disregard for the safety of others requires "despicable conduct," not merely a willful and conscious disregard of a plaintiff's interest].)

Finally, we reject plaintiff's contention that our decision in *Pomona Valley Hospital Medical Center v. Superior Court* (2012) 209 Cal.App.4th 687 compels a different result. Plaintiff quotes the following language from the "Facts and Procedural History" section of our opinion summarizing the IRB provisions of the Hospital's bylaws:

"The stated purpose of the IRB is to provide assurance to the medical staff, the governing board, and the community that the rights and welfare of patients involved in investigational studies are protected and patients are fully informed about the risks involved in the investigational study before they consent. The IRB is charged with responsibility for the evaluation and approval of proposed investigational studies, as well as monitoring ongoing studies. It is the IRB's duty to require that each patient be adequately informed of the nature of the study and the possible side effects, risks and consequences of an investigational drug or device. It is also the IRB's duty to require that each patient sign an informed consent." (*Pomona Valley Hospital Medical Center v. Superior Court, supra*, 209 Cal.App.4th at p. 691.)

We reject plaintiff's contention that the above-quoted language compels a finding that she satisfied her obligation of showing a substantial probability of prevailing on her punitive damages claim against the Hospital. The language correctly describes the duties of the IRB set forth in the Hospital's bylaws. The record presented to respondent court contains no evidence that the IRB failed to monitor whether Dr. Mesiwala, the person "primarily responsible for the conduct of a medical experiment," properly obtained informed consent from the patients in the study. (See Health & Saf. Code, § 24176 [person who is "primarily responsible for conduct of a medical experiment" must obtain a

subject's informed consent]; *Daum v. SpineCare Medical Group, Inc.* (1997) 52 Cal.App.4th 1285, 1319 [“The statutes and federal regulations on which the Daums rely to establish the duty of disclosure clearly hold ‘the investigator’ (21 C.F.R. § 50.20 (1996)) or the ‘person who is primarily responsible for the conduct of a medical experiment’ (Health & Saf. Code, § 24176) responsible for obtaining the subject’s informed consent.”].)

DISPOSITION

The petition for writ of mandate is granted. A peremptory writ shall issue directing respondent court to vacate that portion of its order of September 12, 2012, granting plaintiff’s motion to amend the complaint to add punitive damages allegations under section 425.13. Costs are awarded to petitioner Pomona Valley Hospital Medical Center.

KRIEGLER, J.

We concur:

TURNER, P. J.

FERNS, J.*

* Judge of the Los Angeles Superior Court assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.