No. S220250

1st Civ. No. A137035
(Alameda Superior Court No. RG11-600291)

IN THE SUPREME COURT

OF THE STATE OF CALIFORNIA

PDX, INC. & NATIONAL HEALTH INFORMATION NETWORK, INC.,

Defendants and Appellants,

vs.

KATHLEEN HARDIN & DANE HARDIN,

Plaintiffs and Respondents.

REPLY IN SUPPORT OF PETITION FOR REVIEW

THOMAS R. BURKE (SBN 141930)
ROCHELLE L. WILCOX (SBN 197790)
JEANNE SHEAHAN (SBN 253875)
DAVIS WRIGHT TREMAINE LLP
505 Montgomery Street, Suite 800
San Francisco, California 94111
Tel: (415) 276-6500
Fax: (415) 276-6599

Attorneys for Defendants and Appellants
PDX, INC. and NATIONAL HEALTH INFORMATION NETWORK, INC.

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I. INTRODUCTION

Plaintiffs' Answer to the Petition for Review ignores the reality that the Court of Appeal's published decision holds PDX – and other software vendors – to a no-fault or negligence standard for participating in the distribution of truthful speech that falls squarely within the protection of the First Amendment. The panel's adoption of such a low bar to hold a software vendor liable for true speech distributed with its software is unprecedented and warrants review by this Court.

Plaintiffs insist that the monograph that PDX's software delivered to Safeway was false, although they cannot identify a single false statement. Plaintiffs' actual claim is that the monograph that Safeway elected to give to Mrs. Hardin lacked the warning information that Plaintiffs contend was necessary to protect her.

But it is undisputed that the monograph expressly stated that it "is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects" and "is generalized and [] not intended as specific medical advice." C.T. 131. It also twice directed recipients to read the "Medication Guide." Id. The Court of Appeal's novel ruling – that a software vendor like PDX can be held liable

under a negligence or no-fault liability standard for helping to distribute truthful information that is not legally required, merely because a recipient asserts that it is incomplete – will expose a wide array of content providers and distributors to liability. The panel clearly erred, skewing California law, in summarily rejecting PDX's reliance on the First Amendment to defeat Plaintiffs' claims. Section II.A, infra.

Plaintiffs also wrongly insist that no conflict exists between the panel's decision and a decision from the Fourth District Court of Appeal, Rivera v. First DataBank, Inc., 187 Cal.App.4th 709 (2010). In Rivera, the court dismissed claims against the publisher of a monograph because it was neither the manufacturer of the drug nor the pharmacy, and so it owed no duty to the plaintiffs. Id. at 719. In contrast, the panel here held that PDX owed a duty of care to Plaintiffs. The cases cannot be reconciled except by this Court.

Nor is it true, as Plaintiffs claim, that disputed issues of fact preclude review. The material factual issues are undisputed, and on those undisputed facts, as a matter of law, PDX owed no duty to Plaintiffs. Plaintiffs also largely ignore the law giving PDX the right to rely on the legal obligations held by Mrs. Hardin's physician and

pharmacist, which required them to give her the Medication Guide and the warnings she claims she needed to avoid harm. The panel's decision to find a duty owed by a software vendor like PDX, merely for assisting in distributing information – even if the content itself makes clear that the information is incomplete and refers recipients to the source of more complete information – will reverberate across any number of industries that provide information to third parties. It must be reversed. Section II.B, infra.

Plaintiffs' Answer barely addresses the third issue raised in PDX's Petition, presumably because Plaintiffs abandoned their products liability claim below and cannot defend the panel's decision to keep that claim alive. Plaintiffs' claim plainly is based on PDX's speech that is squarely within the protection of the First Amendment, because the only harm alleged flowed out of the content of the speech delivered using PDX's software. Here too, in potentially subjecting PDX to liability without fault for true speech delivered via a software program that worked exactly as intended, the panel has endorsed a brand new theory of liability against content distributors, without the careful consideration that should have preceded the adoption of such an unprecedented theory. Section II.C, infra.

Plaintiffs' arguments against the application of Section 230 of the Communications Decency Act also find no support in the law. Plaintiffs cannot deny that PDX's conduct of modifying its software at Safeway's request to allow Safeway to print five-section, rather than eight-section, monographs, falls squarely within the broad protection provided by Section 230. The Court of Appeal's decision contradicts settled law on this issue and should be reversed. Section III, infra.

Plaintiff's Answer to the Petition for Review seeks to distract from these dispositive issues. It grossly understates the scope of the Court of Appeal's published decision – including its recognition of two entirely new theories of liability against distributors of content and software providers – in claiming that the Court of Appeal's published decision will have limited reach. Ans. 3-4. In the end, Plaintiff's failure to defend so many aspects of the Court's decision only underscores the fact that the panel's decision is contrary to well-established law, and this Court's review is necessary to "secure uniformity of decision" and "settle [] important question[s] of law." Cal. R. Ct. 8.500(b).

II. REVIEW SHOULD BE GRANTED ON ALL OF THE ISSUES RAISED IN THE PETITION FOR REVIEW

A. The Court of Appeal Rejected PDX's First Amendment Argument on the Merits, and that Issue Properly Is Presented for Review.

Contrary to Plaintiffs' claim, the primary issue presented for review – whether the First Amendment protects PDX in its role in the distribution of consumer product information – squarely was addressed in the Court of Appeal, and that Court rejected PDX's argument on the merits. Ans. 17; see Opinion ("Op.") 13. Plaintiffs ignore most of PDX's arguments (Pet. 18-23), effectively conceding that the panel's decision subjecting PDX to liability is directly contrary to each of the cases that PDX cites. Review should be granted for this reason alone.

Instead of directly responding to PDX's arguments, Plaintiffs accuse PDX of "a material factual misstatement" in PDX's claim that the speech distributed in the monograph was true. Ans. 15. They claim that the monograph's omission of the black box warning constituted an actionable misrepresentation. Id. But Plaintiffs do not explain how this omission could possibly be construed as a misrepresentation, given that the monograph explicitly states that it is incomplete and refers patients to the Medication Guide for complete

information. Pet. 15.[1] Plainly, the monograph did not purport to provide complete information to Plaintiffs.

Regardless, Plaintiffs cite no case to support their claim that PDX can be held liable for allegedly modifying its software, at Safeway's request, to omit information from the monograph, because no case supports them. Their argument confuses the law governing fraud claims with the very different law under the First Amendment. In Winter v. G.P. Putnam's Sons, 938 F.2d 1033, 1037-1038 (9th Cir. 1991), for example, the Ninth Circuit flatly rejected the idea that a book publisher could be held liable for harm allegedly sustained due to incomplete information in the book, explaining that "[w]ere we tempted to create this duty, the gentle tug of the First Amendment and the values embodied therein would remind us of the social costs."

As a matter of law, PDX cannot be held liable merely because the monograph delivered using its software allegedly was incomplete

[1] As Plaintiffs cannot deny, the monograph prominently states that it is "Important to read the Medication Guide before use." C.T. 131 (Item 2, left side of page). It also states, in the second paragraph, "This medicine has a MEDICATION GUIDE approved by the U.S. Food and Drug Administration. Read it carefully." Id. (second sentence in "HOW TO USE THIS MEDICINE" paragraph). Finally, it concludes with the warning that it is incomplete, generalized and "not intended as specific medical advice." Id. (final paragraph).

– particularly where it expressly made clear that that it was incomplete. This Court should grant review to ensure that software providers such as PDX, and other content distributors and providers, are not subjected to unprecedented liability for merely distributing truthful information about a subject, where a plaintiff contends that the speaker did not provide all of the information that the plaintiff would have liked.[2] Permitting liability on these facts exposes content distributors and providers to brand new liability, and will chill speech.

B. The Panel Created A Direct Conflict in the Law on the Issue of Whether a Duty Exists to Provide Comprehensive Information in Publications Such as Drug Monographs.

Plaintiffs invoke the factual differences between this case and Rivera to insist that the cases are distinguishable. Ans. 3. But here too, they ignore the issue presented in the Petition – whether a duty exists to provide comprehensive information in publications like the drug monographs at issue in this case and Rivera. This is a question of law, to be resolved by the court in consideration of the category of allegedly negligent conduct – and not the particular facts of the case.

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[2] Plaintiffs incorrectly claim that PDX failed to raise this issue in the Court of Appeal. Ans. 16. In response to arguments Plaintiffs made in their Answer Brief on appeal, PDX expressly argued that the First Amendment bars negligence claims based on the content of publications. PDX Reply on appeal at 44.

Pet. 37 (citing Ludwig v. City of San Diego, 65 Cal.App.4th 1105, 1111 (1998)). By not addressing the question that PDX has asked the Court to review – indeed, not even mentioning the several monograph cases that PDX cites (see Pet. 22 n.2, 31) – Plaintiffs essentially concede that the Court of Appeal's decision on this issue also is contrary to well-established law.

Plaintiffs also try to muddy the waters by arguing that disputed issues of fact should preclude this Court's review. But again, their arguments only highlight the need for review. Plaintiffs' ongoing reliance on an Action Plan adopted pursuant to Pub.L. No. 104-180 (August 6, 1996), 110 Stat. 1593 – and their suggestion that it imposes a binding obligation on PDX and distributors of consumer medication information – is wrong as a matter of law. Ans. 5-6; see Pet. 12-13, 35 n.5. Tellingly, Plaintiffs have not cited any requirement that drug monographs include black box warnings – or any particular content – because there is no such mandate. As PDX explains in its Petition for Review – and Plaintiffs cannot refute – the Action Plan provides non-binding guidelines. C.T. 771, 789, 791, 797-798 (Action Plan is voluntary). PDX cannot be held liable for doing something that it is not legally required to do, yet this is the faulty premise on which the

Court of Appeal's duty analysis is premised.

Plaintiffs also pay little heed to the undisputed fact that Mrs. Hardin's physician and pharmacist were legally required to give her the warnings that she claims she needed to avoid harm. 21 C.F.R. §§ 201, 208.[3] This does not merely go to the care with which PDX carried out its alleged undertaking, as the Court found and Plaintiffs contend. Ans. 19. Rather, it establishes that PDX did not assume any duty to Plaintiffs, as a matter of law.

As PDX explains in its Petition – and Plaintiffs largely ignore – given the independent legal obligation held by Plaintiff's physician and pharmacist, PDX did not assume a duty to Plaintiffs for three independent reasons: (1) PDX's undertaking was limited to providing

[3] Indeed, Plaintiffs themselves recognize that the duty they seek to impose on PDX actually was held by Mrs. Hardin's pharmacist at Safeway. The Petition for Review that Plaintiffs filed the same day as PDX filed the instant Petition for Review, Case No. 220252, explains that review should be granted in that case because "[a]s a result of the appellate decisions in this case, the software company, PDX, Inc., may be held liable for its alleged negligence in modifying its software (at the request of Safeway, Inc.) to produce only abbreviated drug monographs. Safeway, Inc., however, may not be held liable for its own similar conduct, namely using PDX's software that it knew and intended would produce monographs that omitted drug warnings for all of its pharmacy customers nationwide." Safeway Pet. at 5. Plainly, Plaintiffs agree that any duty to warn that was owed to them was owed by Safeway.

software that would distribute a monograph to supplement advice from Plaintiff's physician and any medication guide required by the FDA, and PDX never undertook to provide a comprehensive warning (Pet. 29-36); (2) Plaintiffs' injuries were not foreseeable because Plaintiff's physician and pharmacist were legally required to give her the very warnings she claims she needed (and that PDX allegedly failed to provide) (Pet. 36-38); and, (3) PDX was entitled to rely on Plaintiff's pharmacist's legal obligation to provide a warning to Plaintiff (Pet. 38-41).

The Court of Appeal's opinion newly creates liability for companies involved in the distribution of speech where none existed before. Before this decision, courts carefully distinguished based on the undertaking actually assumed. A speaker might be held liable if it expressly assumed a duty of care to readers, for example, by providing a guarantee regarding a product being reviewed. E.g., Hanberry v. Hearst Corp., 276 Cal.App.2d 680 (1969). In contrast, if a speaker merely discussed a topic, without providing any commitment about the product's quality or safety, courts consistently rejected liability. E.g., Winter v. G.P. Putnam's Sons, 938 F.2d 1033 (9th Cir. 1991). This careful balance – which is required by the First

Amendment – did not prevail here. The Court of Appeal has, for the first time to PDX's knowledge, found a duty of care without any express undertaking or commitment. The Court's flawed analysis opens the door to liability for a wide array of speakers and companies that support distribution of truthful speech. It is a dangerous precedent, and should be reversed.

C. The Court of Appeal's Refusal to Strike Plaintiffs' Products Liability Claim Is Unprecedented, and Will Subject Content Providers to Liability Without Fault.

Plaintiffs barely mention the Court of Appeal's unprecedented ruling that PDX can be held liable on a products liability theory for harm allegedly caused by a product that PDX does not manufacture or distribute, solely because its software distributed truthful information about that product, which Plaintiffs allege was incomplete. Ans. 20; see Pet. 41-45. PDX is aware of no case permitting no fault liability for speech protected by the First Amendment, and neither Plaintiffs nor the panel cite such a case.

Despite the unprecedented specter of the Court of Appeal's imposition of no-fault liability against a company involved in the distribution of truthful information that someone else authored, Plaintiffs' only response is that their products liability claim should

not be resolved on an anti-SLAPP motion because PDX's motion was presented at an early stage of the litigation. Ans. 20. That argument turns the anti-SLAPP statute on its head.

The anti-SLAPP statute is designed to weed out meritless lawsuits early in the case, to ensure that defendants such as PDX are not dragged through litigation on claims that plaintiffs cannot substantiate. See Cal. Code Civ. Proc. § 425.16(a); see, e.g., Briggs v. Eden Council for Hope & Opportunity, 19 Cal.4th 1106, 1121-1123 (1999). Plaintiffs bore the burden of stating and substantiating a legally sufficient claim. Id. at 1123 (citations omitted); see also Taus v. Loftus, 40 Cal.4th 683, 713-714 (2007); Navellier v. Sletten, 106 Cal.App.4th 763, 776 (2003). If Plaintiffs needed discovery to meet their burden, they were required to ask permission to conduct discovery before the hearing on the motion. Cal. Code Civ. Proc. § 425.16(g). They did not.

Plaintiffs cannot escape their failure to meet their burden by the blithe claim that they should be allowed to conduct discovery now to support their products liability claim. Opening this door – exposing software providers to liability without fault where the software worked exactly as intended – is unprecedented. This is particularly

true because for the first time under California law, truthful speech that is distributed through software is now subject to no fault products liability. This Court should grant review and ensure that the Court of Appeal's poorly-reasoned decision does not become the law in California, or anywhere else.

D. The Court of Appeal's Misapplication of Section 230 of the Communications Decency Act Will Create Confusion and Discord in Application of that Statute.

Plaintiffs claim that the immunity provided by Section 230 of the Communications Decency Act does not apply here because Mrs. Hardin received the monograph in hard copy from her pharmacy, not by accessing a website. Ans. 21. But it is irrelevant how a plaintiff ultimately obtains the information. Rather, Section 230 immunity turns on whether (1) the defendant provides or uses an "interactive computer service," (2) the claim treats the defendant as the "publisher or speaker" of content, and (3) that content is provided "by another information content provider." 47 U.S.C. § 230(c)(1). See Pet. 46.

All of these elements are satisfied here. PDX provides and uses an interactive computer service because its software facilitates access by Safeway to Wolters Kluwer Health, Inc. ("WKH") monographs, through a server. C.T. 38-39. Plaintiffs' claims are based on the

content of the monograph, meaning they treat PDX as its publisher. Finally, PDX obtained the monograph content from WKH – who exclusively authored and updated the content of the monographs that Safeway gave to its customers. As set forth in the Petition for Review, the fact that PDX altered its software so that Safeway would only receive five section monographs, at Safeway's request, does not transform it into the provider of the content. See Pet. 48-49.

Plaintiffs posit that under PDX's interpretation, "the seller of a physical product that used an 'interactive computer service' to create the paper label could avoid the traditional seller's product liability for failure to warn," Ans. 21, but this hypothetical compares apples to oranges. In selling a physical product, the seller is not acting as the provider or user of an interactive computer service and is therefore entirely outside the scope of Section 230 immunity. Thus, in this case, Safeway, in printing the monograph and supplying it to Mrs. Hardin, is not a provider or user of an interactive computer service; Safeway has no Section 230 defense

Plaintiffs' second hypothetical is similarly flawed. Plaintiffs suggest that under PDX's view, "a publisher could download defamatory information … print it in a newspaper and deliver it to

newsstands." Ans. 21. But again, the publisher of a newspaper is not acting as the provider or user of an interactive computer service when it publishes a print publication. So, too, Safeway here is not entitled to Section 230 immunity merely because it obtained the monograph content through an interactive computer service.

In contrast, in both hypotheticals, the interactive computer service itself (that is, the service from whom the seller and newspaper, respectively, obtained the information) may be entitled to Section 230 immunity if that information originated with a third party. This is exactly what happened here. The monograph content was exclusively supplied by WKH and shortened at Safeway's request by PDX, and thus PDX was not the "information content provider" for any of the allegedly unlawful content. It is therefore entitled to immunity. See Gentry v. eBay, Inc., 99 Cal.App.4th 816, 831 (2002) (rejecting attempt to hold eBay liable for representations as to authenticity of physical goods supplied by third parties; imposing liability would be "treating [eBay] as the publisher, viz., the original communicator, contrary to Congress's expressed intent under section 230(c)(1) and (e)(3).").

III. CONCLUSION

The Court of Appeal's published decision opens the door to a wide array of litigation, imposing a startling burden on companies that facilitate the distribution of speech protected by the First Amendment. Its breadth inevitably will chill speech – not only by software providers such as PDX, but by any content distributor or provider that discusses a product that might cause harm. It skews established California law, and should be reversed.

PDX therefore respectfully requests that this Court grant review of each of the Issues presented in the Petition for Review and, on review, reverse the decision by the Court of Appeal, and enter an Order directing the trial court to grant PDX's Special Motion to Strike under California Code of Civil Procedure § 425.16 in its entirety.

Respectfully submitted this ____ day of August, 2014

DAVIS WRIGHT TREMAINE LLP

By _____
Thomas R. Burke

Attorneys for Defendants and Appellants

PDX, INC. and NATIONAL HEALTH INFORMATION NETWORK, INC.

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COMPLIANCE CERTIFICATE

I am a partner in the law firm of Davis Wright Tremaine LLP, I certify that pursuant to Rule of Court 8.504(d), the attached Reply in Support of Petition for Review is proportionately spaced, has a typeface of 14 points, and according to the word processing systems used to prepare this Petition contains 3,283 words, including footnotes, but excluding the caption, tables, this certificate, and signature blocks.

Dated: August ____, 2014

DAVIS WRIGHT TREMAINE LLP

By _____
Thomas R. Burke

Attorneys for Defendants and Appellants

PDX, INC. and NATIONAL HEALTH INFORMATION NETWORK, INC.