Filed 7/21/14 (unmodified opn. attached)

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION THREE

KATHLEEN HARDIN et al., Plaintiffs and Respondents, v. PDX, INC., et al., Defendants and Appellants.	A137035 (Alameda County Super. Ct. No. RG11600291) ORDER MODIFYING OPINION AND DENYING REHEARING NO CHANGE IN JUDGMENT

THE COURT:

It is ordered that the opinion filed herein on June 19, 2014, is modified as follows:

At page 12, immediately preceding the last sentence of the first paragraph, insert the following text: PDX also asserts that Hardin cannot prevail on her products liability theory as a matter of law because PDX distributes drug information, and " 'information' is not a 'product' for purposes of product liability claims." But Hardin's theory is that *PDX's software program*, not the information it produces, is the defective product. PDX has not argued, let alone shown, that Hardin cannot prevail under that theory. Maybe so, but at this early juncture we cannot so conclude. (See *Yu v. Signet Bank/Virginia*, *supra*, 103 Cal.App.4th at p. 318 ["The causes of action need only be shown to have 'minimal merit.' "].)

The petition for rehearing is denied. There is no change in the judgment.

DATE: _____

McGuiness, P.J.

Filed 6/19/14 (Unmodified version)

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION THREE

KATHLEEN HARDIN et al., Plaintiffs and Respondents, v. PDX, INC., et al., Defendants and Appellants.	A137035 (Alameda County Super. Ct. No. RG11600291)

PDX, Inc. claims the trial court erred when it denied a motion to strike brought under Code of Civil Procedure section 425.16, and refused to dismiss a negligence and product liability action as a Strategic Lawsuit Against Public Participation. Because the plaintiff demonstrated a probability she may prevail on her claim, we affirm.

BACKGROUND

Kathleen Hardin suffered complete blindness and permanent, severe and painful scarring after she began taking Lamotrigine, the generic form of the medication Lamictal. According to her complaint, Hardin later learned that Lamotrigine carries a significant risk of causing Stevens-Johnson syndrome (SJS) and associated toxic epidermal necrolysis that resulted in her injuries, particularly when taken in combination with another of her prescribed medications.

Hardin and her husband[1] filed suit for negligence and product liability against multiple defendants, including the physician who prescribed her Lamotrigine, GlaxoSmithKline, which manufactured it, Safeway, Inc., where she purchased it, and

[1]For simplicity, we will refer to plaintiffs jointly as Hardin.

Wolters Kluwer Health, Inc. (WKH), which produced the drug information pamphlet, or monograph, Safeway provided when it filled Hardin's prescription. WKH monographs offer summaries of information from official FDA physician package inserts and patient medication guides written in lay language for consumers and are intended to provide a written supplement to the oral counseling patients receive from their pharmacists when they have a prescription filled. (See generally *Rivera v. First DataBank, Inc.* (2010) 187 Cal.App.4th 709, 713 (*Rivera*).) Unlike physician package inserts and patient medication guides, which are FDA-mandated, WKH monographs are not regulated or reviewed by the FDA. Rather, the monographs are produced as part of a self-regulating action plan required under public law as approved by the Secretary of the United States Department of Health and Human Services. (Pub.L. No. 104-180 (Aug. 6, 1996) 110 Stat. 1593.)

The action plan summarizes its goal by stating: "The purpose of this Action Plan is to improve the quality and availability of useful information that is voluntarily provided to consumers with their prescription medicines. The rationale for the Plan is that providing consumers with useful information about their prescription medicines can reduce the risk of preventable, medication-induced injury and improve health outcomes." The action plan goes on to describe useful information as "that which is sufficiently comprehensive and communicated such that consumers can make informed decisions about how to receive the most benefit from medicines and protect themselves from harm. Both the substance and presentation of the information are important." Nevertheless, each monograph states that it is not intended to be a comprehensive statement of all risks and benefits of the medication and cautions consumers against relying solely on the monograph for information about the medication.

There does not seem to be any material factual dispute about the nature of PDX's activities. As explained in the declaration of Benjamin Loy, PDX's vice president of industry relations, in support of the motion to strike, PDX is "an independent provider of software that distributes drug information to pharmacy customers." One component of its business involves disseminating patient drug education monographs authored by third parties. To that end, its software "enables pharmacies to access [WKH's] database of

Monographs. WKH is an independent publisher of medical information for the general public concerning drugs approved for sale by the FDA. . . . [¶] PDX, Inc. does not author the Monographs but instead, provides this information under an authorization in the data license agreement between NHIN, PDX, Inc.'s affiliated company, and WKH." PDX and NHIN thus "function as pass through entities to distribute Monographs that are prepared by WKH to retailers selling prescription drugs like Safeway" and are printed and distributed to the individual customer when a prescription is filled.

Decisions about the content of these monographs were made by Safeway, not by PDX. According to Mr. Loy, "WKH, as the [data] owner and licensor, writes, formats, develops and updates the drug product information that PDX accesses through its license with WKH. Neither PDX nor NHIN modify the drug product information in any manner whatsoever." Prior to 2005, PDX's software enabled its licensees to print out either the long (eight-section) or short (five-section) version of the monograph for any given drug. The short version excluded sections under the headings "Before Using This Medication," "Overdose," and "Additional Information." The "Before Using This Medication" section contains warnings about taking the drug that may include warnings about drug interactions or complications due to coexisting medical conditions. In 2005, in response to regulatory guidelines, PDX revised its software so that it would no longer print the abbreviated monographs. For reasons not clear from the record, Safeway did not want to utilize the full eight-section monographs and asked PDX to revise its software so that Safeway could continue to print only the five-section versions. PDX complied with that request after it obtained a release of liability and indemnity agreement from Safeway.

The WKH monograph was the only information received by Hardin when she first filled her prescription for Lamictal, and the only patient information she considered in deciding whether to take the medication. The abbreviated warning utilized by Safeway and provided to Hardin omitted what is referred to as the "Black Box" warning under the heading "BEFORE USING THIS MEDICINE" that stated: "SERIOUS AND SOMETIMES FATAL RASHES HAVE OCCURRED RARELY WITH THE USE OF THIS MEDICINE. . . . Contact your doctor immediately if you develop rash symptoms,

including red, swollen, blistered or peeling skin. Treatment with this medication should be stopped unless it is clearly determined that the medicine did not cause the rash. Even if the medicine is stopped, a rash caused by this medicine may still become life-threatening or cause serious side effects (such as permanent scarring)." Hardin says that had she been provided this warning, she would not have taken the medication.

WKH moved to strike Hardin's claims against it under Code of Civil Procedure[2] section 425.16 (the "anti-SLAPP" statute) on the ground that the products liability and negligence claims against it arose from protected speech concerning a public issue or an issue of public interest. The trial court ruled that WKH's production of drug monographs was protected speech under section 425.16, subdivision (e)(4) and that Hardin had no probability of prevailing on her claims because, following the rationale of *Rivera, supra*, 187 Cal.App.4th 709, she could not establish that WKH owed her any duty. Accordingly, the court granted WKH's motion and dismissed the claims against it.

Hardin amended her complaint to allege causes of action for negligence and products liability against PDX, Inc. and National Health Information Network, Inc. (NHIN).[3] PDX also moved under the anti-SLAPP statute to strike Hardin's claims, which it argued were identical to the dismissed claims against WKH and barred for the same reasons.

This time, the trial court disagreed. It determined that the activity underlying PDX's alleged liability was the reprogramming of its software to permit Safeway to give customers an abbreviated, five-section monograph that omitted warnings about SJS instead of the full eight-section version that included those warnings. "Plaintiffs have asserted acts by PDX that go beyond mere distribution of the WKH's monographs. Plaintiffs assert that in 2005 PDX revised its software program to prevent its customers, including Safeway, 'from printing the five section abbreviated monograph and allowed

[2]Unless otherwise noted, further statutory citations are to the Code of Civil Procedure.

[3]Jointly referred to as PDX.

only the printing of the complete eight section monograph.' [Citation.] According to Mr. Loy, Senior Vice President of Industry Relations for PDX, Inc. and National Health Information Network Inc., [citation], '[t]his software revision was made in response to both regulatory guidelines for the provision of patient education information and an internal recommendation by Jim Boyd, R.Ph., then Sr. Vice President [of] Network Services NHIN.' [Citation.] Then, in 2006, a Safeway representative contacted PDX because it wanted to use the five section monograph, rather than the eight section monograph with the warnings at issue here. [Citation.] In response, '[p]rogramming to allow the system to provide the five section monograph was made available by PDX [] to Safeway. . . .' [Citation.] Given these facts, this is not a case in which a defendant merely distributed information from a third party author or publisher."

The court concluded that PDX's reprogramming activities were not acts in furtherance of the defendant's right of petition or free speech within the meaning of section 425.16 and denied PDX's motion to strike. PDX filed a timely appeal from the court's order. (See § 904.1, subd. (a)(13).)

DISCUSSION

I. The Anti-SLAPP Statute

Unmeritorious claims that are brought to thwart constitutionally protected speech or petitioning activity may be stricken pursuant to a motion filed under Code of Civil Procedure section 425.16. (See *Mann v. Quality Old Time Service, Inc.* (2004) 120 Cal.App.4th 90, 102.) This anti-SLAPP statute provides: "(b)(1) A cause of action against a person arising from any act of that person in furtherance of the person's right of petition or free speech under the United States Constitution or the California Constitution in connection with a public issue shall be subject to a special motion to strike, unless the court determines that the plaintiff has established that there is a probability that the plaintiff will prevail on the claim. [¶] . . . [¶] (e) As used in this section, 'act in furtherance of a person's right of petition or free speech under the United States

Constitution or the California Constitution in connection with a public issue' includes: (1) any written or oral statement or writing made before a legislative, executive, or judicial proceeding, or any other official proceeding authorized by law, (2) any written or oral statement or writing made in connection with an issue under consideration or review by a legislative, executive, or judicial body, or any other official proceeding authorized by law, (3) any written or oral statement or writing made in a place open to the public or a public forum in connection with an issue of public interest, or (4) any other conduct in furtherance of the exercise of the constitutional right of petition or the constitutional right of free speech in connection with a public issue or an issue of public interest." (§ 425.16.) "The only way a defendant can make a sufficient threshold showing is to demonstrate that the conduct by which the plaintiff claims to have been injured falls within one of those four categories." (*Weinberg v. Feisel* (2003) 110 Cal.App.4th 1122, 1130.)

We consider an anti-SLAPP motion in a two-step process. "First, the court decides whether the defendant has made a threshold showing that the challenged cause of action is one arising from protected activity. The moving defendant's burden is to demonstrate that the act or acts of which the plaintiff complains were taken 'in furtherance of the [defendant]'s right of petition or free speech under the United States or California Constitution in connection with a public issue,' as defined in the statute. (§ 425.16, subd. (b)(1).) If the court finds such a showing has been made, it then determines whether the plaintiff has demonstrated a probability of prevailing on the claim. Under section 425.16, subdivision (b)(2), the trial court in making these determinations considers 'the pleadings, and supporting and opposing affidavits stating the facts upon which the liability or defense is based.' " (*Equilon Enterprises v. Consumer Cause, Inc.* (2002) 29 Cal.4th 53, 67 (*Equilon*).)

We review the trial court's determinations as to whether the plaintiff has shown a probability of prevailing independently. (*ComputerXpress, Inc. v. Jackson* (2001) 93

Cal.App.4th 993, 999.) An anti-SLAPP motion does not survive this prong " 'if the plaintiff presents evidence establishing a prima facie case which, if believed by the trier of fact, will result in a judgment for the plaintiff. [Citation.]' " (*Fleishman v. Superior Court* (2002) 102 Cal.App.4th 350, 356.) We neither " ' "weigh credibility [nor] compare the weight of the evidence. Rather, [we] accept as true the evidence favorable to the plaintiff [citation] and evaluate the defendant's evidence only to determine if it has defeated that submitted by the plaintiff as a matter of law." [Citation.]' " (*Nygard, Inc. v. Uusi-Kerttula* (2008) 159 Cal.App.4th 1027, 1036 (*Nygard*).) "In order to satisfy due process, the burden placed on the plaintiff must be compatible with the early stage at which the motion is brought and heard [citation] and the limited opportunity to conduct discovery." (*Wilcox v. Superior Court* (1994) 27 Cal.App.4th 809, 823, disapproved on other grounds in *Equilon, supra*, 29 Cal.4th at p. 68, fn. 5.) Only a minimal showing of merit is required. (*Yu v. Signet Bank/Virginia* (2002) 103 Cal.App.4th 298, 318.)

We affirm if the trial court's decision is correct for any reason, regardless of the correctness of the grounds upon which it reached its conclusion. (*In re Estate of Beard* (1999) 71 Cal.App.4th 753, 776.)

II. Analysis

The trial court based its ruling on its conclusion that PDX's role in the production and dissemination of the short-form monograph Hardin received was not "conduct in furtherance of the exercise of the constitutional right of petition or the constitutional right of free speech in connection with a public issue or an issue of public interest," and, thus, was beyond the scope of section 425.16, subdivision (e)(4). We need not answer this interesting question, for, assuming arguendo that Hardin's claims against PDX arose from protected first amendment activity, if credited at trial her evidence would be sufficient to support a favorable judgment. (See *Taus v. Loftus* (2007) 40 Cal.4th 683, 713–714 [plaintiff's burden opposing anti-SLAPP motion is to state and substantiate a legally sufficient claim]; *Nygard, supra*, 159 Cal.App.4th at p. 1044.)

A. *Rivera v. First Databank, Inc. Is Factually Inapposite*

PDX argues that Hardin's negligence claim fails under *Rivera v. First DataBank, Inc.* (2010) 187 Cal.App.4th 709. It maintains *Rivera* holds that, as a matter of law, PDX has no duty to consumers who receive drug monographs through its software. We are not persuaded that *Rivera* controls here.

The plaintiffs' decedent in *Rivera* committed suicide shortly after he began taking the anti-depressant drug Paxil. First DataBank, Inc. (First DataBank) published the drug monograph Rivera received from his pharmacist. The plaintiffs alleged the monograph omitted the FDA's black-box suicide warnings for Paxil, and that the warnings it included were vague, confusing, and buried in fine print. (*Rivera, supra,*187 Cal.App.4th at pp. 713–714.) The trial court denied the motion (*id.* at p. 714), but the court of appeal reversed. After concluding that the lawsuit targeted protected speech (§ 425.17, subd. (c)), the court held that the plaintiffs had not shown a likelihood of success at trial because they failed to establish First DataBank owed them a legal duty. (*Rivera, supra,* 187 Cal.App.4th at p. 719.) First, it noted, the plaintiffs presented no evidence supporting their allegation that the monograph omitted the black box warning. (See *Nagel v. Twin Laboratories, Inc.* (2003) 109 Cal.App.4th 39, 45 ["plaintiff cannot rely on the allegations of the complaint alone, but must present admissible evidence"].) Second, the allegedly omitted warning would not have applied to the 50-year old Rivera because it warned of suicide risks only among children and adolescents. (*Rivera, supra,* 187 Cal.App.4th at p. 719.)

This case is different. Unlike *Rivera,* here there was evidence that the black-box warning had been deleted from the monograph Hardin received with her prescription. Hardin attested that "[t]he Wolters Kluwer Health medicine information monograph I received, read and relied upon in deciding to take Lamictal/Lamotrigine did not include the section which is in capital letters and starts with WARNING: SERIOUS AND SOMETIMES FATAL RASHES HAVE OCCURRED RARELY WITH THE USE OF

THIS MEDICINE, that the rashes warned about appear as red, swollen, blistered, peeling skin and that the rashes warned about could be life-threatening even if you stop taking the medication and that the rashes warned about could cause serious side effects such as permanent scarring." The evidence Hardin submitted also contains the abbreviated monograph described in her declaration alongside the full eight-section monograph complete with the omitted warnings. In further contrast to *Rivera*, the omitted sections, if included, would have applied to *all* potential consumers of Lamotrigine. The evidentiary shortcomings presented in *Rivera* are not present here.

B. Rivera Does Not Address The Negligent Undertaking Doctrine

Rivera is also of limited precedential value for another reason: it does not address Hardin's theory that, in undertaking to provide patient drug monographs, PDX assumed a duty of care under the negligent undertaking doctrine. (See *Ginns v. Savage* (1964) 61 Cal.2d 520, 524 fn. 2 ["Language used in any opinion is of course to be understood in the light of the facts and the issue then before the court"].) This common law theory, restated in section 324A of the Restatement (Second) of Torts (hereinafter section 324A), "is one of liability to third persons for physical harm caused when, under certain listed circumstances, one negligently performs an undertaking to another. In its entirety, section 324A reads: 'One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to [perform] his undertaking, if [¶] (a) his failure to exercise reasonable care increases the risk of such harm, or [¶] (b) he has undertaken to perform a duty owed by the other to the third person, or [¶] (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.' [¶] . . . Indeed, '[i]t is ancient learning that one who assumes to act . . . may thereby become subject to a duty of acting carefully, if he acts at all. [Citation] As 'Dean Prosser says . . . , "[i]f the defendant enters upon an affirmative course of conduct affecting the

interests of another, he is regarded as assuming a duty to act, and will thereafter be liable for negligent acts or omissions[.]" ' " (*Artiglio v. Corning Inc.* (1998) 18 Cal.4th 604, 612–613 (*Artiglio*).)

FNS Mortgage Service Corp. v. Pacific General Group, Inc. (1994) 24 Cal.App.4th 1564 is illustrative. The defendant, IAPMO, promulgated a uniform plumbing code, certified plumbing products that met its standards, and published a directory listing certified products. The owners and developers of an apartment complex sued IAPMO for property damage allegedly caused by defective, IAPMO-certified drain, waste and vent pipe. (*Id*. at pp. 1566–1570.) Citing section 324A, the court of appeal held that IAPMO assumed the duty to exercise reasonable care in carrying out its enterprise when it voluntarily undertook to identify pipe manufacturers that adhered to its standards for the consuming public. (*Id*. at p. 1572; see also *Hanberry v. Hearst Corp.* (1969) 276 Cal.App.2d 680, 684 [publisher that conducted product endorsement program assumed a duty of ordinary care to consumers who relied on its endorsement].) Other jurisdictions, although apparently no California courts, have considered that parties who engage in providing medication warnings to consumers may be found to have assumed a duty to use due care in carrying out their enterprise. (See *Neeley v. Wolters Kluwer Health, Inc.* (E.D.Mo. July 30, 2013 No. 4:11-cv-325-JAR) 2013 U.S. Dist. Lexis 106191*13 [failure to warn claims targeting WKH monographs withstood motion to dismiss under assumption of duty principles]; *Slater v. Hoffman-La Roche Inc.* (E.D. Pa. 2011) 771 F.Supp.2d 524, 527–528 [negligent undertaking theory of duty withstood frivolous joinder challenge]; *Cottam v. CVS Pharmacy* (Mass. 2002) 764 N.E.2d 814, 821–823 [where patient could reasonably interpret warning provided by pharmacy as complete list of all known side effects, pharmacist's duty was "commensurate with what it appeared to have undertaken"].)

Here, Hardin presented evidence that PDX knew that enabling Safeway to print the abbreviated monograph could place patients at risk, including, notably, the

acknowledgement in its 2006 agreement with Safeway that providing the full eight-section version would better enable patients to "use the medication properly and appropriately, receive the maximum benefit, and avoid harm." This record sufficiently makes out a claim that PDX assumed a duty of care by undertaking to render services to Safeway "of a kind [it] should have recognized as necessary for the protection of third persons. . . ." (*Artiglio, supra,* 18 Cal.4th at p. 604).

Citing *Rivera*, PDX also argues it had no duty to Hardin because the abbreviated Lamotrigine monograph included a warning that it did not cover all possible adverse effects and advised patients to read the medication guide and consult their physicians before taking the medication. We disagree with PDX's view that, as a matter of law, this language has any bearing upon the scope of its duty. The cited provisos and their foreseeable effect on consumers are relevant to whether PDX acted with due care when it enabled Safeway to omit warnings from WKH monographs, but it is the nature of PDX's undertaking, not the care with which it was carried out, that determines whether it assumed a duty under section 324A in the first place.

PDX's remaining arguments merit only brief attention. PDX claims Hardin failed to show causation, but her declaration says the WKH monograph was the only medication information she received, that she read and relied on it, and that she would not have taken Lamotrigine had it included a warning about serious or fatal rashes. PDX also asserts Evidence Code section 1155[4] bars Hardin from relying upon the indemnity clause in PDX's 2006 agreement with Safeway to prove negligence, but, assuming the indemnity language is inadmissible, there is no reason to believe its exclusion would prevent Hardin from proving her case.

PDX's claim that section 230 of the federal Communications Decency Act (47 U.S.C. § 230, hereinafter CDA) immunizes it from liability for providing electronic

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[4]Under Evidence Code section 1155, "Evidence that a person was, at the time a harm was suffered by another, insured wholly or partially against loss arising from liability for that harm is inadmissible to prove negligence or other wrongdoing."

access to WKH monographs is also unpersuasive. "The CDA provides that (1) '[n]o provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider' and (2) '[n]o cause of action may be brought and no liability may be imposed under any State or local rule that is inconsistent with this section.' [Citation.] Section 230(f)(2) defines 'interactive computer service' as 'any information service, system, or access software provider that provides or enables computer access by multiple users to a computer service, including specifically a service or system that provides access to the Internet[.]' An 'information content provider' is 'any person or entity that is responsible, in whole or in part, for the creation or development of information provided through the Internet or any other interactive computer service.' [Citation.] 'Congress clearly enacted § 230 to forbid the imposition of publisher liability on a service provider for the exercise of its editorial and self-regulatory functions.' " (*Anthony v. Yahoo! Inc.* (N.D. Cal. 2006) 421 F.Supp.2d 1257, 1262 (*Anthony*).)

Hardin's claim against PDX does not arise from its role as the software or service provider that enabled Safeway to access the WKH Lamotrigine monograph. Hardin sued PDX because it intentionally modified its software to allow Safeway to distribute abbreviated drug monographs that automatically omitted warnings of serious risks. As the trial court found, "this is not a case in which a defendant merely distributed information from a third party author or publisher." PDX cites, and we are aware of, no case holding the CDA to have immunized a defendant from allegations that it participated in creating or altering content. (See *Anthony, supra*, 421 F.Supp.2d at pp. 1262–1263.) "One need look no further than the face of the statute to see why. The CDA only immunizes 'information provided by *another* information content provider.' (47 U.S.C. § 230(c)(1).)" (*Id.* at p. 1263.)

PDX also asserts that the First Amendment and Civil Code section 47, subdivision (d)[5] immunize it from liability for distributing what it describes as "truthful summaries of the FDA's Package Insert and Medication Guide." It has not been established at this juncture that WKH's monographs are "truthful summaries" of official FDA proceedings, that they qualify as "public journals" for purposes of the section 47, subdivision (d) privilege, or that they "do nothing to dilute" the warnings in FDA-approved mediation guides and package inserts and are not otherwise misleading. PDX's evidence has not defeated that submitted by Hardin as a matter of law (see *Nygard, supra,* 159 Cal.App.4th at p. 1036), so its anti-SLAPP motion was properly denied.

DISPOSITION

The order denying PDX's anti-SLAPP motion is affirmed.

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Siggins, J.

We concur:

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McGuiness, P.J.

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Pollak, J.

[5]Civil Code section 47 privileges a publication or broadcast "made [¶] . . . [¶] (d)(1) By a fair and true report in, or a communication to, a public journal, of (A) a judicial, (B) legislative, or (C) other public official proceeding, or (D) of anything said in the course thereof . . . ."

Trial Court:	Alameda County Superior Court
Trial Judge:	Honorable Gail Brewster Bereola
Counsel for Appellants:	Thomas R. Burke Jeff Glasser Jeanne Sheahan DAVIS, WRIGHT, TREMAINE LLP
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