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U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

Plaintiff-Appellant,

v.

XAVIER BECERRA, in his Official
Capacity as Attorney General of the State
of California,

Defendant-Appellee.

No. 20-15014

D.C. No.
2:19-cv-02281-TLN-DB

MEMORANDUM*

Appeal from the United States District Court
for the Eastern District of California
Troy L. Nunley, District Judge, Presiding

Argued and Submitted July 16, 2020
San Francisco, California

Before: IKUTA and HURWITZ, Circuit Judges, and TAGLE,** District Judge.

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

** The Honorable Hilda G. Tagle, United States District Judge for the Southern District of Texas, sitting by designation.

In this interlocutory appeal, Association for Accessible Medicine (AAM) challenges the denial of its motion for a preliminary injunction against the enforcement of California Assembly Bill 824 (AB 824).

Although the district court analyzed the complaint in terms of ripeness, “[t]he doctrines of standing and ripeness ‘originate’ from the same Article III limitation” and “boil down to the same question.” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157 n.5 (2014) (citation omitted); *see also Coons v. Lew*, 762 F.3d 891, 897 (9th Cir. 2014). We therefore analyze the Article III requirements in terms of standing here.

To establish standing, “[t]he plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). The injury in fact must be “concrete, particularized, and actual or imminent.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013) (citation omitted). Plaintiffs suffer an injury in fact if they incur economic harm in complying with a statute. *See Mont. Shooting Sports Ass’n v. Holder*, 727 F.3d 975, 979–81 (9th Cir. 2013); *Nat’l Audubon Soc’y, Inc. v. Davis*, 307 F.3d 835, 855–56 (9th Cir. 2002). When plaintiffs allege a future injury, the injury must be “certainly impending,” or there must be “a ‘substantial risk’ that the

harm will occur,” to satisfy the requirements of standing. *Clapper*, 568 U.S. at 410, 414 n.5 (citation omitted). Where the future injury alleged is the enforcement of an allegedly unconstitutional statute, “a plaintiff satisfies the injury-in-fact requirement where he alleges ‘an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.’” *Susan B. Anthony List*, 573 U.S. at 159 (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)).

“The party invoking federal jurisdiction bears the burden of establishing standing.” *Id.* at 158 (citation omitted). “[E]ach element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.” *Id.* (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)). “Therefore, at the preliminary injunction stage, a plaintiff must make a ‘clear showing’ of his injury in fact.” *Lopez v. Candaele*, 630 F.3d 775, 785 (9th Cir. 2010) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)).

AAM has not shown that there is a “substantial risk” that AB 824 will cause any of its members to suffer injury that is concrete, particularized, and imminent. *Clapper*, 568 U.S. at 414 n.5.

First, to the extent that AB 824 chills or prohibits “pay for delay” settlement agreements,¹ none of the declarations that AAM members have submitted in support of AAM’s motion for preliminary injunction allege “an intention to engage in a course of conduct arguably affected with a constitutional interest,” *Susan B. Anthony List*, 573 U.S. at 159 (citation omitted), i.e., an intention to engage in such a settlement. At most, AAM’s members state that they are engaged in patent-infringement lawsuits involving pharmaceutical products and that they historically have settled such lawsuits, but they do not allege that they intend to enter into settlement agreements of the sort prohibited by AB 824. Thus, AAM has not established standing based on a threat of imminent or “certainly impending” prosecution. *Clapper*, 568 U.S. at 410.

Second, AAM members have not established that they have incurred economic injury due to complying with AB 824, i.e., by foregoing pay for delay settlements or litigating patent-infringement suits to judgment. Rather, the

¹ Specifically, AB 824 provides that “an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, shall be presumed to have anticompetitive effects and shall be a violation of this section” if (1) “[a] nonreference drug filer receives anything of value from another company asserting patent infringement” and (2) “[t]he nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer’s product for any period of time.” 2019 Cal. Legis. Serv. Ch. 531 (West) (codified at Cal. Health & Safety Code § 134002(a)(1)).

members state that they “likely would expect to be forced to litigate every pending patent-infringement lawsuit to judgment,” or that they “likely will stay [their] hand on many products and simply stay off the market until the relevant patents all expire.” These declarations allege only “*possible* future injury” and do not establish a substantial risk of harm. *Clapper*, 568 U.S. at 409 (citation omitted).

Because AAM has not demonstrated that its members have an Article III injury in fact, we conclude that AAM lacks associational standing to bring claims on its members’ behalf. *See Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 342 (1977). We vacate the district court’s order and remand with instructions to dismiss without prejudice.

VACATED AND REMANDED with instructions.²

² Costs are awarded to appellee.

United States Court of Appeals for the Ninth Circuit

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Information Regarding Judgment and Post-Judgment Proceedings

Judgment

- This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

Mandate (Fed. R. App. P. 41; 9th Cir. R. 41-1 & -2)

- The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate ECF system or, if you are a pro se litigant or an attorney with an exemption from using appellate ECF, file one original motion on paper.

Petition for Panel Rehearing (Fed. R. App. P. 40; 9th Cir. R. 40-1)

Petition for Rehearing En Banc (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3)

(1) A. Purpose (Panel Rehearing):

- A party should seek panel rehearing only if one or more of the following grounds exist:
 - ▶ A material point of fact or law was overlooked in the decision;
 - ▶ A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
 - ▶ An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Purpose (Rehearing En Banc)

- A party should seek en banc rehearing only if one or more of the following grounds exist:

- ▶ Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
- ▶ The proceeding involves a question of exceptional importance; or
- ▶ The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing may be filed within 14 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- *See* Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-2.

(3) Statement of Counsel

- A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- An answer, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or answer must be accompanied by a Certificate of Compliance found at Form 11, available on our website at www.ca9.uscourts.gov under *Forms*.
- You may file a petition electronically via the appellate ECF system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

Bill of Costs (Fed. R. App. P. 39, 9th Cir. R. 39-1)

- The Bill of Costs must be filed within 14 days after entry of judgment.
- See Form 10 for additional information, available on our website at www.ca9.uscourts.gov under *Forms*.

Attorneys Fees

- Ninth Circuit Rule 39-1 describes the content and due dates for attorneys fees applications.
- All relevant forms are available on our website at www.ca9.uscourts.gov under *Forms* or by telephoning (415) 355-7806.

Petition for a Writ of Certiorari

- Please refer to the Rules of the United States Supreme Court at www.supremecourt.gov

Counsel Listing in Published Opinions

- Please check counsel listing on the attached decision.
- If there are any errors in a published opinion, please send a letter **in writing within 10 days** to:
 - ▶ Thomson Reuters; 610 Opperman Drive; PO Box 64526; Eagan, MN 55123 (Attn: Jean Green, Senior Publications Coordinator);
 - ▶ and electronically file a copy of the letter via the appellate ECF system by using “File Correspondence to Court,” or if you are an attorney exempted from using the appellate ECF system, mail the Court one copy of the letter.

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT
Form 10. Bill of Costs**

Instructions for this form: <http://www.ca9.uscourts.gov/forms/form10instructions.pdf>

9th Cir. Case Number(s)

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