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JUL 24 2020

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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NOT FOR PUBLICATION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.