

Attachment A

FILED

JUL 26 2023

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

HOPE MEDICAL ENTERPRISES, INC.,
DBA Hope Pharmaceuticals,

Plaintiff-Appellee,

v.

FAGRON COMPOUNDING SERVICES,
LLC; et al.,

Defendants-Appellants.

No. 22-55173

D.C. No.
2:19-cv-07748-CAS-PLA

MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
Christina A. Snyder, District Judge, Presiding

Argued and Submitted July 21, 2023
Pasadena, California

Before: S.R. THOMAS, NGUYEN, and FORREST, Circuit Judges.

Fagron Compounding Services, LLC and others (“Fagron”) appeal the district court’s judgment in favor of Hope Medical Enterprises, Inc. (“Hope”) in Hope’s diversity action alleging Fagron violated state unfair-competition laws by

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

selling prescription drugs prohibited by state drug-approval laws. We have jurisdiction pursuant to 28 U.S.C. § 1291. Following a bench trial, we review the district court’s conclusions of law de novo. *Oakland Bulk & Oversized Terminal, LLC v. City of Oakland*, 960 F.3d 603, 612 (9th Cir. 2020). We also review a district court’s decision regarding preemption de novo. *Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1287 (9th Cir. 2021). We reverse.¹ Because the parties are familiar with the factual and procedural history of the case, we need not recount it here.

Federal law preempts state law when the state requirement “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1231 (9th Cir. 2013) (en banc) (citation omitted). The federal Food, Drug, and Cosmetic Act (“FDCA”) prohibits private enforcement: “all proceedings to enforce or restrain violations of the FDCA must be ‘by and in the name of the United States,’ except for certain proceedings by state governments.” *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1044 (9th Cir. 2022) (quoting 21 U.S.C. § 337(a)). The FDCA regulates the manufacturing of compounded drugs and exempts manufacturers of compounded drugs from the requirement to obtain drug

¹ We also deny Fagron’s motion for judicial notice (Dkt. 32).

approval from the Food and Drug Administration (“FDA”) in certain instances. *Id.* at 1042–43; 21 U.S.C. §§ 353a–b.

In *Nexus*, we held that the FDCA preempted a pharmaceutical company’s suit alleging that another pharmaceutical company violated several states’ unfair-competition laws by selling an unapproved, compounded drug that was “essentially a copy” of an FDA-approved drug under section 503B of the FDCA. *Id.* at 1044. We reasoned that the FDCA’s prohibition on private enforcement bars a drug manufacturer from suing another drug manufacturer for economic harm “because the defendant violated the FDCA.” *Id.* at 1050.

Nexus controls here. Because Hope seeks to “enforce its interpretation” of the FDCA’s rules for manufacturing compounded drugs against a competitor, the FDCA’s prohibition on private enforcement and the doctrine of implied preemption bar the suit. *Id.* at 1050–51.

We also reverse the district court’s award of fees and costs to Hope.

REVERSED.

Attachment B

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UNITED STATES COURT OF APPEALS

OCT 2 2023

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Central District of California,

Los Angeles

ORDER

Before: S.R. THOMAS, NGUYEN, and FORREST, Circuit Judges.

The full court has been advised of the petition for rehearing en banc, and no judge of the court has requested a vote on the petition for rehearing en banc. Fed.

R. App. P. 35(b).

The appellee's petition for rehearing en banc is DENIED.