

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMARIN PHARMA, INC., AMARIN	:	
PHARMACEUTICALS IRELAND	:	
LIMITED, MOCHIDA	:	
PHARMACEUTICAL CO., LTD.,	:	
	:	
Plaintiffs,	:	
v.	:	C.A. No. 20-1630-RGA
	:	
HIKMA PHARMACEUTICALS USA	:	
INC., HIKMA PHARMACEUTICALS	:	
PLC,	:	
	:	
Defendants.	:	

**DEFENDANTS’ OPENING BRIEF IN
SUPPORT OF MOTION TO DISMISS**

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NATURE AND STAGE OF THE PROCEEDINGS

Defendants, Hikma Pharmaceuticals USA Inc. and Hikma Pharmaceuticals PLC (together, “Hikma”) are pharmaceutical companies committed to providing patients with high-quality essential medicines. Hikma manufactures oral, nasal, and sterile-injectable medicines across a diversified portfolio, including many of the medicines most needed to treat seriously ill COVID-19 patients. Over the past 10 years, Hikma has invested hundreds of millions of dollars in building and expanding its US and global manufacturing capabilities and seeks to bring more affordable generic medicines to market.

Plaintiffs (collectively, “Amarin”) filed this case alleging that Hikma’s launch of a generic version of Amarin’s Vascepa actively induces infringement of U.S. Patent Nos. 9,700,537 (“the ’537 patent”), 8,642,077 (“the ’077 patent”), and 10,568,861 (“the ’861 patent”) (collectively, “patents-in-suit”). Hikma moves to dismiss under Rule 12(b)(6).

SUMMARY OF ARGUMENT

Amarin’s current lawsuit is its latest attempt to stifle legitimate generic competition for its sole product, a branded fish-oil product called Vascepa (icosapent ethyl). Amarin previously filed—and lost—a Hatch-Waxman patent infringement lawsuit to prevent Hikma from bringing its generic icosapent ethyl product to market. In March 2020, the U.S. District Court for the District of Nevada found all patents asserted against Hikma’s generic icosapent ethyl product (with its sole indication to treat severely high triglyceride levels) invalid as obvious, and, in September 2020, the Federal Circuit summarily affirmed. *Amarin Pharma, Inc. v. Hikma Pharms. USA*, 449 F. Supp. 3d 967 (D. Nev. 2020), *aff’d*, 819 F. App’x 932 (Fed. Cir. 2020), *reh’g denied*, 2020-1723, D.I. 90 (Fed. Cir. Nov. 4, 2020).

Hikma subsequently launched its generic product in early November 2020. Amarin then filed this second lawsuit (in a different jurisdiction), alleging that Hikma’s labeling and website,

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