UNITED STATES PATENT AN	D TRADEMARK OFFICE
BEFORE THE PATENT TRIAL	 L AND APPEAL BOARD
APOTEX 1	INC.
Petitione	er.

v.

UCB BIOPHARMA SPRL, Patent Owner.

Case IPR2019-00400 Patent 8,633,194

PATENT OWNER COMPLETE RESPONSE



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### **TABLE OF AUTHORITIES**

r:	age(s)
CASES	
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rendi SARL v. Apple Inc., 832 F.3d 1355 (Fed. Cir. 2016)	.3, 46
Comaper Corp. v. Antec, Inc., 596 F.3d 1343 (Fed. Cir. 2010)	49
verett Laboratories, Inc. v. Breckenridge Pharm., Inc., 573 F. Supp. 2d 855 (D.N.J. Aug. 26, 2008)	37
Falderma Labs., LP v. Tolmar, Inc., 737 F. 3d 731 (Fed. Cir. 2013)	4
Voneywell Int'l Inc. v. Mexichem Amanco Holding S.A. DE C.V., 865 F.3d 1348 (Fed. Cir. 2017)	49
n re Clay, 966 F.2d 656 (Fed. Cir. 1992)	42
n re Coutts, 726 Fed. Appx. 791 (Fed. Cir. 2018)	39
n re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063 (Fed. Cir. 2012)	.3, 47
n re Gurley, 27 F.3d 551 (Fed. Cir. 1994)	47
n re Magnum Oil Tools Int'l, Ltd., 829 F.3d 1364 (Fed. Cir. 2016)	29, 34
n re Papesch, 315 F.2d 381 (C.C.P.A. 1963)	48



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