

Filed: February 10, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

and

DR. REDDY'S LABORATORIES, INC.,

Petitioner¹

v.

HORIZON PHARMA USA, INC. and NUVO PHARMACEUTICALS
(IRELAND) DESIGNATED ACTIVITY COMPANY.

Patent Owners

Case No. IPR2017-01995

U.S. Patent No. 9,220,698

PATENT OWNERS' MOTION TO TERMINATE

¹ Petitioner Dr. Reddy's Laboratories, Inc., from IPR2018-00894, has been joined as a Petitioner to this proceeding

TABLE OF CONTENTS

	Page
I. Background.....	1
II. The Board Has Authority to Terminate These Proceedings.....	4
III. Petitioners Cannot Meet their Burden of Showing that the Claims Are Unpatentable	4
IV. Proceeding Would be a Waste of the Board’s Resources	8

TABLE OF AUTHORITIES

Page

Cases

<i>Blackberry Corp. v. MobileMedia Ideas, LLC</i> , IPR2013-00036, Paper 65 (P.T.A.B. Mar. 7, 2014)	4, 5
<i>Comtech Mobile Datacom Corp. v. Vehicle IP, LLC</i> , Case IPR2018-00531, Paper 9 (P.T.A.B. July 20, 2018)	8, 9
<i>Enzo Biochem, Inc. v. Applera Corp.</i> , 599 F.3d 1325 (Fed. Cir. 2010)	5
<i>Facebook, Inc. v. EveryMD.com LLC</i> , Case IPR2017-02027, Paper 24 (P.T.A.B. Oct. 9, 2018)	4
<i>Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.</i> , 839 F.3d 1382 (Fed. Cir. 2016)	4
<i>Microsoft Corp. v. IpLearn-Focus, LLC</i> , IPR2015-00097, Paper 11 (P.T.A.B. Mar. 26, 2015)	5, 6, 7
<i>In re Steele</i> , 305 F.2d 859 (C.C.P.A. 1962)	5
<i>United Carbon Co. v. Binney & Smith Co.</i> , 317 U.S. 228 (1942)	5

Other Authorities

37 C.F.R.	
§ 42.71(a)	1, 4
§ 42.72	1, 4

Pursuant to the Board's Order dated January 25, 2019 (IPR2017-01995, Paper No. 60), Patent Owners, Horizon Pharma USA, Inc. and Nuvo Pharmaceuticals (Ireland) Designated Activity Company, submit this Motion to Terminate the *Inter Partes* Review of U.S. Patent No. 9,220,698 ("the '698 patent"). Corresponding motions will be filed concurrently in co-pending Case Nos. IPR2018-00272 and IPR2018-01341 involving U.S. Patent No. 9,393,208 ("the '208 patent").

The Board should dismiss the Petition pursuant to 37 C.F.R. § 42.71(a) and terminate this *inter partes* review pursuant to 37 C.F.R. § 42.72 for two reasons. First, Petitioners cannot meet their burden of demonstrating by a preponderance of the evidence that the challenged claims are unpatentable because the district court has found that under Petitioners' own construction, the claims are indefinite. Second, because of the late stage of the district court litigation and pending appeal to the Federal Circuit, proceeding with this *inter partes* review would not be an effective use of the Board's resources.

I. Background

The claims of the '698 patent require administering AM and PM unit dose forms that provide 500 mg of naproxen and 20 mg of esomeprazole and that "target" particular pharmacokinetic (PK) and pharmacodynamic (PD) profiles for naproxen and esomeprazole. Ex. 1001 at 52:25-38 (claim 1).

The parties began litigating the '698 patent in February 2016 and the '208 patent in December 2016 in the District of New Jersey. In November 2017, the district court issued its Markman Order construing the claims of the '698 and '208 patents. Ex. 2073. The court adopted Petitioners' proposed construction of the term "target" as used in claim 1 of both patents to mean "set as a goal." *Id.* at 11. Fact discovery closed in December 2017 and expert discovery closed in July 2018.

On August 10, 2018, Petitioners moved for summary judgment that the claims of the '698 and '208 patents are invalid as indefinite. Ex. 2074. Petitioners argued that under the court's construction of "target," the claims of both patents are indefinite because "[n]othing in the claims, the specification, or the prosecution history allows those skilled in the art to discern with any reasonable certainty where the boundaries of the asserted claims lie." *Id.* at 2. According to Petitioners, the claims are merely aspirational and "provide no discernable standard for how far a particular formulation administered to any given patient or group of patients can stray from the stated goals and still infringe the claims." *Id.* at 10. Petitioners also argued that the claims are indefinite because they do not specify "who or what must 'target'" the PK and PD profiles in the claims. *Id.* at 16-18.

The district court granted Petitioner's motion because it found the claims of the '698 and '208 patents to be "incomprehensible." Ex. 2075 at 10. The district

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