

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX, INC.
Petitioner,

v.

UCB BIOPHARMA SPRL
Patent Owner.

U.S. Patent No. 8,633,194 to Fanara *et al.*

Issue Date: January 21, 2014

Title: Pharmaceutical composition of piperazine derivatives

Inter Partes Review No.: IPR2019-00400

Petitioner's Reply to Patent Owner's Preliminary Response

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TABLE OF CONTENTS

I. INTRODUCTION 1

II. INSTITUTION SHOULD NOT BE DENIED BASED ON §325(D).....2

 A. Petitioner's Asserted Grounds Are Not Cumulative of Art
 Considered during Prosecution (*Becton* Factors (a-d)).....3

 B. Petitioner Advances Arguments That Were Not Made during
 Prosecution (*Becton* Factor (d)).6

 C. Petitioner Has Pointed out Sufficiently How the Examiner Erred
 in Its Evaluation of the Asserted Prior Art (*Becton* Factor (e)).7

 D. Additional Evidence and Facts Presented in the Petition Warrant
 Reconsideration of the Prior Art (*Becton* Factor (f)).9

III. THE *GENERAL PLASTIC* FACTORS DO NOT SUPPORT DENIAL
OF INSTITUTION UNDER §314(A)..... 10

IV. CONCLUSION..... 10

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Actavis LLC v. Abraxis Bioscience, LLC</i> , IPR2017-01103 Paper 7 (October 10, 2017).....	8, 9
<i>Becton, Dickinson and Company v. B. Braun Melsungen AG</i> , IPR2017-01586, slip op. (PTAB Dec. 15, 2017).....	<i>passim</i>
<i>General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha</i> , IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017).....	10
<i>In re Peterson</i> , 315 F.3d 1325 (Fed. Cir. 2003)	9
<i>Intel Corp. v. Godo Kaisha IP Bridge 1</i> , IPR2018-00753, Paper No. 11	5
<i>Koios Pharms. LLC v. medac Gesellschaft für klinische Spezialpräparate mbH</i> , IPR2016-01370, Paper 13 (PTAB Feb. 8, 2017).....	7
<i>Microsoft Corp. v. Saint Regis Mohawk Tribe</i> , IPR2018-01594, Paper 21 (PTAB April. 12, 2019).....	1, 10
<i>Quanergy Systems, Inc. v. Velodyne Lidar, Inc.</i> , IPR2018-00256, Paper 14 (PTAB May 25, 2018)	7
<i>Samsung Elecs. Co. Ltd. v. Immersion Corp.</i> , IPR2018-01499, Paper 11 (Mar. 6, 2019)	1
Statutes	
35 U.S.C. § 314(a)	1, 10
35 U.S.C. § 325(d)	<i>passim</i>

I. INTRODUCTION

Apotex Inc.'s ("Apotex") Petition demonstrated that *inter partes* review ("IPR") should be instituted for all challenged claims of U.S. Patent No. 8,633,194 ("the '194 patent"). UCB Biopharma Sprl ("UCB" or "Patent Owner") does not dispute **any** substantive argument advanced by Apotex. Instead, UCB limits its Preliminary Response ("POPR") to unavailing §325(d) and §314(a) arguments.

UCB's implicit contention under 35 U.S.C. § 325(d) seems to be that if an Examiner applies a reference for a limitation during prosecution, then *any* other reference for that limitation would be *per se* cumulative. This interpretation of §325(d) is untenable, effectively insulating every patent from *inter partes* review. The PTAB expects some degree of similarity between an IPR Petition and the events that occurred during patent prosecution. *Samsung Elecs. Co. Ltd. v. Immersion Corp.*, IPR2018-01499, Paper 11, at 13 (Mar. 6, 2019) ("[a]ny similarity of the art in this proceeding to art previously applied to [the claim] is due to the fact that any ground applied to [the claim] must address the subject matter of [that claim]."). Unremarkably, similarity alone is not a basis to exercise §325(d) discretion. *Id.* at 12-13. Then, UCB tries to invoke §314(a) when the corresponding District Court case is stayed. "[T]here are no inefficiencies associated with this proceeding because the parallel proceeding is stayed pending this proceeding." *Microsoft Corp. v. Saint Regis Mohawk Tribe*, IPR2018-01594, Paper 21 at 11 (PTAB April. 12, 2019).

II. INSTITUTION SHOULD NOT BE DENIED BASED ON §325(D)

Petitioner put forth two grounds of unpatentability in its Petition:

Ground	References	Basis	Claims Challenged
1	WO '094 in view of the Handbook	§ 103	1-11
2	EP '203 in view of US '558 and the Handbook	§ 103	1-11

The Examiner never rejected any claim of the '194 patent based on WO '094, EP '203, US '558 and/or the Handbook. Nor did the Examiner even discuss WO '094, EP '203, or US '558 during prosecution. UCB does not dispute this. POPR at 9 (UCB admitting "Petitioner's prior art references may not have expressly been the subject of an office action."). Rather, Patent Owner alleges that WO '094, the Handbook, and EP '203 were fully considered by the Examiner by the mere act of citing them on an information disclosure statement ("IDS"). POPR at 2, 4-6, 9, 12, 13, 25. Applicable PTAB guidance suggests otherwise.

The PTAB has consistently declined exercising its discretion under §325(d) when all a Patent Owner can do is show a reference was disclosed on an IDS but not applied by the Examiner. Pet. at 65-66 (citing multiple PTAB cases). As explained in its Petition and herein, the asserted Grounds are not cumulative of the art considered during prosecution. Further, as discussed below, all of the *Becton, Dickinson and Company v. B. Braun Melsungen AG* factors weigh against the Board

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