

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TWI PHARMACEUTICALS, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00050
Patent 8,377,903

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

	Page
I. Introduction.....	1
II. Background.....	5
III. Person Of Ordinary Skill In The Art	7
IV. Claim Construction.....	7
V. The Petition Should Be Denied Under 35 U.S.C. § 325(d).....	8
A. The Office Already Considered Petitioner’s Alleged Prior Art And Arguments	10
1. <i>Becton Dickinson</i> Factors (a) And (b): Asserted Art Was Considered During Examination.....	10
2. <i>Becton Dickinson</i> Factor (d): Petitioner’s And The Examiner’s Arguments Are Not Materially Different	11
B. Petitioner Has Not Identified A Material Error By The Examiner	13
1. <i>Becton Dickinson</i> Factor (c): Asserted Art Was Evaluated During Examination.....	14
2. <i>Becton Dickinson</i> Factor (e): Petitioner Has Not Identified Any Examiner Error.....	15
3. <i>Becton Dickinson</i> Factor (f): Additional Evidence Does Not Warrant Reconsideration	20
VI. Petitioner Is Not Reasonably Likely To Prevail On Any Ground.....	21
A. Ground I – Bodor Does Not Anticipate	21

1.	Ground I Is Based On An Incorrect Interpretation Of The Law	21
2.	Bodor Does Not Disclose All Claim Limitations Expressly, Inherently, Or By Inference	25
a)	Bodor Does Not Disclose RRMS or early SPMS	25
b)	Bodor Does Not Disclose Induction Period Dose Of About 1.7 Or 1.7-3.5 Mg/Kg Or Maintenance Period Dose Of About 1.7 Mg/Kg	27
c)	Bodor Does Not Disclose The Claimed Maintenance Period Or “Cladribine-Free Period” Thereafter	32
B.	Ground II – The Challenged Claims Are Not Obvious Over Bodor ..	41
1.	Bodor Does Not Disclose Or Suggest All Claim Limitations ..	41
2.	Petitioner Has Not Established Any Motivation To Modify Bodor’s Method to Arrive At The Challenged Claims.....	42
3.	Petitioner Has Not Established Any Reasonable Expectation Of Success In Modifying Bodor’s Method to Arrive At The Challenged Claims	49
C.	Ground III – The Challenged Claims Are Nonobvious Over Bodor And Rice.....	54
1.	Bodor And Rice Fail To Disclose Or Suggest All Claim Limitations	55
2.	Petitioner Has Not Established Any Motivation To Modify Bodor’s Method In View Of Rice To Arrive At The Challenged Claims	57

3. Petitioner Has Not Established Any Reasonable Expectation Of
Success In Combining Bodor With Rice To Arrive At The
Challenged Claims61

VII. Objective Indicia Support Non-Obviousness63

VIII. Conclusion63

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Acoustic Tech., Inc. v. Itron Networked Sols., Inc.</i> , 949 F.3d 1366 (Fed. Cir. 2020)	22
<i>Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GmbH</i> , IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020).....	<i>passim</i>
<i>Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc.</i> , 344 F.3d 1186 (Fed. Cir. 2003)	23
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG</i> , IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017)	10
<i>Bettcher Indus. v. Bunzl USA, Inc.</i> , 661 F.3d 629 (Fed. Cir. 2011)	22
<i>In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat.</i> <i>Litig.</i> , 676 F.3d 1063 (Fed. Cir. 2012)	49
<i>Dayco Products, Inc. v. Total Containment, Inc.</i> , 329 F.3d 1358 (Fed. Cir. 2003)	30
<i>Eli Lilly & Co. v. L.A. Biomedical Rsch. Inst. at Harbor-UCLA Med.</i> <i>Ctr.</i> , 849 F.3d 1073 (Fed. Cir. 2017)	24
<i>Eli Lilly & Co. v. Teva Pharms. Int’l GmbH</i> , 8 F.4th 1331 (Fed. Cir. 2021)	8
<i>Ex Parte Ramsey</i> , No. 2009-3451, 2009 WL 3044465 (B.P.A.I. Sept. 22, 2009).....	23, 33
<i>Forest Lab’ys, Inc. v. Ivax Pharms., Inc.</i> , 438 F. Supp. 2d 479 (D. Del. 2006).....	26, 29, 34

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.