

UNITED STATES PATENT AND TRADEMARK OFFICE

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

TWI PHARMACEUTICALS, INC.,  
Petitioner,

v.

MERCK SERONO S.A.,  
Patent Owner.

---

Case IPR2023-00050  
U.S. Patent 8,377,903

---

**PATENT OWNER'S RESPONSE**

## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	STATE OF THE ART .....	3
A.	MS .....	3
1.	MS Treatment as of 2004.....	4
2.	MS Outcome Measures.....	4
3.	Cladribine.....	5
B.	Alleged Prior Art.....	6
1.	Bodor (Ex. 1029).....	6
2.	Rice (Ex. 1008) .....	6
III.	'903 PATENT.....	7
IV.	POSA .....	7
V.	CLAIM CONSTRUCTION .....	8
VI.	BODOR'S REGIMEN IS NOT "BY ANOTHER" .....	9
A.	Petitioner fails to meet its burden to show Bodor's regimen is "by another" .....	10
B.	Bodor's regimen is not "by another" .....	12
VII.	THE CHALLENGED CLAIMS ARE PATENTABLE .....	17
A.	Ground I – Bodor Does Not Anticipate .....	17
1.	Petitioner Misinterprets Anticipation Jurisprudence .....	17
2.	Bodor Does Not Disclose All Claim Limitations .....	20

B.	Ground II – Claims Are Non-Obvious Over Bodor and a POSA’s Knowledge .....	37
1.	Bodor Does Not Disclose Or Suggest All Claim Limitations .....	38
2.	No Motivation Or Reasonable Expectation of Success .....	38
C.	Ground III – Claims Are Non-Obvious Over Bodor and Rice .....	52
1.	Bodor and Rice Fail to Disclose or Suggest All Claim Limitations .....	52
2.	No Motivation or Reasonable Expectation of Success in Combining Bodor and Rice .....	54
VIII.	OBJECTIVE INDICIA SUPPORT NONOBVIOUSNESS OF THE CLAIMS .....	58
A.	Skepticism Of Others .....	59
B.	Unexpected Results .....	61
C.	Satisfaction of a Long-Felt, Unmet Need .....	62
D.	Nexus.....	64
IX.	CONCLUSION.....	66

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Federal Cases</b>	
<i>Acoustic Tech., Inc. v. Itron Networked Sols., Inc.</i> , 949 F.3d 1366 (Fed. Cir. 2020) .....	18
<i>Akamai Techs., Inc. v. Cable &amp; Wireless Internet Servs., Inc.</i> , 344 F.3d 1186 (Fed. Cir. 2003) .....	18, 19
<i>Dayco Prods., Inc. v. Total Containment, Inc.</i> , 329 F.3d 1358 (Fed. Cir. 2003) .....	23
<i>In re DeBaun</i> , 687 F.2d 459 (C.C.P.A. 1982).....	9, 17
<i>Duncan Parking Techs., Inc. v. IPS Grp., Inc.</i> , 914 F.3d 1347 (Fed. Cir. 2019) .....	10
<i>Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.</i> , 800 F.3d 1375 (Fed. Cir. 2015) .....	11
<i>Eli Lilly &amp; Co. v. L.A. Biomedical Rsch. Inst. at Harbor-UCLA Med. Ctr.</i> , 849 F.3d 1073 (Fed. Cir. 2017) .....	19
<i>Eli Lilly &amp; Co. v. Teva Pharms. Int’l GmbH</i> , 8 F.4th 1331 (Fed. Cir. 2021) .....	8
<i>In re Jasinski</i> , 508 F. App’x 950 (Fed. Cir. 2013).....	8
<i>In re Kubin</i> , 561 F.3d 1351 (Fed. Cir. 2009) .....	58
<i>In re Land</i> , 368 F.2d 866 (C.C.P.A. 1966).....	10
<i>Neptune Generics, LLC v. Eli Lilly &amp; Co.</i> , 921 F.3d 1372 (Fed. Cir. 2019) .....	61

*Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*,  
851 F.3d 1270 (Fed. Cir. 2017) .....20

*Pitney Bowes, Inc. v. Hewlett-Packard Co.*,  
182 F.3d 1298 (Fed. Cir. 1999) .....8

*Quanergy Sys., Inc. v. Velodyne Lidar USA, Inc.*,  
24 F.4th 1406 (Fed. Cir. 2022) .....65

*Rambus Inc. v. Rea*,  
731 F.3d 1248 (Fed. Cir. 2013) .....65

*Riverwood Int’l Corp. v. R.A. Jones & Co.*,  
324 F.3d 1346 (Fed. Cir. 2003) .....11

*Takeda Chem. Indus. v. Alphapharm Pty.*,  
492 F.3d 1350 (Fed. Cir. 2007) .....58

*Unigene Lab’ys, Inc. v. Apotex, Inc.*,  
655 F.3d 1352 (Fed. Cir. 2011) .....51

*Verdegaal Bros. v. Union Oil Co. of Cal.*,  
814 F.2d 628 (Fed. Cir. 1987) .....17, 21

*Volvo Penta of the Americas, LLC v. Brunswick Corp.*,  
81 F.4th 1202 (Fed. Cir. 2023) .....58

*WBIP, LLC v. Kohler Co.*,  
829 F.3d 1317 (Fed. Cir. 2016) .....59

**Federal Statutes**

35 U.S.C. § 102(a) .....9, 10

35 U.S.C. § 102(b) .....9

35 U.S.C. § 102(e) .....9, 10

# 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.