

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner

v.

**NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,**
Patent Owner

Case IPR2020-01317
Patent 9,220,631

**NOVARTIS PHARMA AG, NOVARTIS TECHNOLOGY LLC, AND
NOVARTIS PHARMACEUTICALS CORPORATION'S
PATENT OWNER PRELIMINARY RESPONSE**

TABLE OF CONTENTS

I.	Introduction.....	1
II.	The Board Should Exercise Its Discretion and Deny Institution	5
A.	The <i>Fintiv</i> Factors Compel Denial of Institution Based on Concurrent ITC Proceedings.....	6
1.	Factor 1 (stay of proceedings).....	8
2.	Factor 2 (proximity of trial date to projected deadline for final written decision)	9
3.	Factor 3 (investment in the ITC proceeding).....	11
4.	Factor 4 (overlap of issues).....	12
5.	Factor 5 (same parties).....	14
6.	Factor 6 (other circumstances).....	14
B.	The Board Should Exercise Its Discretion Under Section 325(d) and Decline Institution Because the Art and Arguments Relied on in the Petition are Substantially the Same as What Was Addressed During Prosecution.....	15
1.	The Asserted Art is not Materially Different from Art Evaluated by the Examiner During Prosecution (<i>Becton Dickinson</i> Factors (a) and (b)).	17
2.	The Examiner Evaluated and Rejected Arguments that Essentially Overlap with Those Presented by Petitioner (<i>Becton Dickinson</i> Factor (d)).....	22
3.	The Examiner Extensively Evaluated Art and Arguments Essentially Similar to Those Asserted by Petitioner, and Developed a Thorough Record (<i>Becton Dickinson</i> Factor (c)).....	25
4.	Petitioner Has Neither Pointed Out How the Examiner Erred in Her Evaluation of the Prior Art nor Identified Additional Evidence or Facts That Warrant Reconsideration of the Prior Art or Arguments (<i>Becton Dickinson</i> Factors (e) and (f)).	27

III.	Person of Ordinary Skill and Claim Construction.....	28
IV.	Petitioner Has Failed to Carry Its Burden of Proving that there is a Likelihood that any CHallenged Claim is Unpatentable.....	28
A.	The Claims of the '631 Patent Would Not Have Been Obvious Over The Combination of Sigg and Boulange (Ground 1).....	28
1.	Petitioner Ignores Key Disclosures in Sigg.	29
2.	Petitioner Ignores Key Disclosures of Boulange.....	33
3.	Petitioner Fails to Show Why a POSA Would Have Been Motivated To Combine Sigg and Boulange to Make the Claimed Invention.....	35
4.	Petitioner Ignores Prior Art Teachings and Fails to Demonstrate that A POSA Would Have had a Reasonable Expectation of Success in Combining Sigg and Boulange.....	39
B.	The Petition Fails to Address Secondary Considerations Supporting the Non-obviousness of the Claimed Inventions.	42
C.	Claims 1–26 of the '631 Patent would not have been obvious over the combination of Sigg and Boulange (Grounds 1–5).	45
V.	Conclusion	47

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Advanced Bionics, LLC. V. Med-El Elektromedizinische Gerate GMBH,</i> No. IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....	6, 17, 25, 28
<i>Apple Inc. v. Fintiv Inc.,</i> IPR2020-00019, Paper 11 (PTAB, March 20, 2020)	<i>passim</i>
<i>Apple Inc. v. Fintiv Inc.,</i> IPR2020-00019, Paper 15 (PTAB, May 13, 2020)	9, 15
<i>Apple Inc. v. Maxell, Ltd.,</i> IPR2020-00203, Paper 12 (PTAB July 6, 2020)	10
<i>Becton, Dickinson and Co. v. B. Braun Melsungen AG,</i> No. IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)	<i>passim</i>
<i>Cisco Sys., Inc. v. Ramot at Tel Aviv University Ltd.,</i> IPR2020-00122, Paper 15 (PTAB May 15, 2020)	9, 14, 15
<i>Crocs, Inc. v. Int’l Trade Comm.,</i> 598 F.3d 1294 (Fed. Cir. 2010)	42, 43
<i>Cuozzo Speed Techs., LLC v. Lee,</i> 136 S. Ct. 2131 (2016).....	5
<i>In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.,</i> 676 F.3d 1062 (Fed. Cir. 2012)	44
<i>Ecolchem, Inc. v. S. California Edison Co.,</i> 227 F.3d 1361 (Fed. Cir. 2000)	39
<i>Fitbit, Inc. v. Koninklijke Philips N.V.,</i> IPR2020-00772, Paper 14 (P.T.A.B. Oct. 19, 2020).....	<i>passim</i>
<i>In re Fritch,</i> 972 F.2d 1260 (Fed. Cir. 1992)	29

<i>Harmonic Inc. v. Avid Tech., Inc.</i> , 815 F.3d 1356 (Fed. Cir. 2016)	5
<i>Impax Labs. Inc. v. Lannett Holdings Inc.</i> , 893 F.3d 1372 (Fed. Cir. 2018)	44
<i>Intel Corp. v. VLSI Tech. LLC</i> , IPR2020-00106, Paper 17 (PTAB May 5, 2020)	10
<i>Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.</i> , 821 F.3d 1359 (Fed. Cir. 2016)	39
<i>KSR Int’l Co. v. Teleflex, Inc.</i> , 550 U.S. 398 (2007).....	35, 36
<i>Mylan Pharm. Inc. v. Research Corp. Techs., Inc.</i> , 914 F.3d 1366 (Fed. Cir. 2019)	46
<i>NHK Spring Co. v. Intri-Plex Techs., Inc.</i> , IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018).....	6, 10
<i>Novartis Pharma AG, et al. v. Regeneron Pharmaceuticals, Inc.</i> , 1:20-cv-690 (S.D.N.Y. July 30, 2020).....	xi
<i>Novartis Pharma AG v. Regeneron Pharm. Inc.</i> , 1:20-cv-00690 (N.D.N.Y.).....	8
<i>Polaris Indus., Inc. v. Arctic Cat, Inc.</i> , 882 F.3d 1056 (Fed. Cir. 2018)	38
<i>Regents of Univ. of Cal. v. Broad Inst., Inc.</i> , 903 F.3d 1286 (Fed. Cir. 2018)	39
<i>Samsung Electronics America, Inc. v. Uniloc 2017 LLC</i> , IPR2019-01218, Paper 7 (PTAB Jan. 7, 2020)	10
<i>Stryker Corp. v. KFX Medical, LLC</i> , IPR2019-00817, Paper 10 (PTAB Sept. 16, 2019).....	43
<i>Supercell Oy v. Gree, Inc.</i> , IPR2020-00310, Paper 13 (PTAB June 18, 2020)	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.