

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LIMITED
Petitioner,

v.

GILEAD SCIENCES, INC.,
Patent Owner.

Case No. IPR2025-00033
U.S. Patent No. 11,744,802

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	Introduction.....	1
II.	Background.....	4
	A. The '802 Patent	4
	B. The District Court Litigation Involving The '802 Patent Is At An Advanced Stage And Involves Three Distinct Defendants.....	8
III.	Claim Construction.....	10
IV.	Level Of Ordinary Skill In The Art.....	11
V.	The Board Should Exercise Its Discretion To Deny This Petition Under § 314(a).....	13
	A. Factor 1 Favors Denial: The District Court Is Not Likely To Grant A Stay	14
	B. Factor 2 Favors Denial: The District Court's Trial Date Is Six Months Before The Projected Statutory Deadline For The PTAB's Final Written Decision	16
	C. Factor 3 Favors Denial: The District Court And The Parties Have Significantly Invested In The District Court Proceeding	18
	D. Factor 4 Favors Denial: The Same Claims, Grounds, Arguments, And Evidence Are At Issue In The Petition And In The Parallel Proceeding	23
	E. Factor 5 Favors Denial: Cipla Is The Petitioner And A Defendant In The District Court.....	26
	F. Factor 6 Favors Denial: The Petition Does Not Present A Compelling Case Of Unpatentability	27
	1. The Merits Of The Petition Are Not Compelling.....	29
	a. A Skilled Artisan Would Not Have Selected 50 Milligrams Of Bictegravir Based On Dolutegravir	29

b.	Gilead’s Solution To An Unexpected And Surprising Problem Was Not Obvious	33
2.	The District Court Is Better Suited To Evaluate The Issues Here Because Of Additional Highly Relevant Evidence Before That Court	36
3.	The Examiner Considered The Art And Teachings Of Petitioner’s Grounds	37
VI.	The Board Should Exercise Its Discretion To Deny This Petition Under § 325(d).....	38
A.	<i>Advanced Bionics</i> Part 1: The Same Or Substantially The Same Prior Art Was Previously Presented To The Patent Office.....	39
B.	<i>Advanced Bionics</i> Part 2: Petitioner Has Not Demonstrated That The Office Erred	44
VII.	Conclusion	48

TABLE OF AUTHORITIES

Cases

<i>10x Genomics, Inc. v. President & Fellows of Harvard Coll.</i> , No. IPR2023-01299, 2024 WL 993828 (PTAB Mar. 7, 2024).....	21, 22, 23
<i>Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.</i> , 764 F.3d 1366 (Fed. Cir. 2014)	47, 48
<i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. PGR2023-00041, 2024 WL 249517 (PTAB Jan. 23, 2024)	44
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH</i> , No. IPR2019-01469, 2020 WL 740292 (PTAB Feb. 13, 2020)	passim
<i>Alarm.com, Inc. v. Vivint, Inc.</i> , No. IPR2022-00728, 2022 WL 16579639 (PTAB Nov. 1, 2022)	41, 44
<i>Apple Inc. v. Fintiv, Inc.</i> , No. IPR2020-00019, 2020 WL 2126495 (PTAB Mar. 20, 2020).....	passim
<i>Apple Inc. v. Fintiv, Inc.</i> , No. IPR2020-00019, 2020 WL 2486683 (PTAB May 13, 2020).....	16, 18, 27, 29
<i>AT&T Servs. Inc. v. Asus Tech. Licensing Inc.</i> , No. IPR2024-00992, 2024 WL 5126018 (PTAB Dec. 16, 2024).....	18, 29
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG</i> , No. IPR2017-01586, 2017 WL 6405100 (PTAB Dec. 15, 2017).....	41
<i>Bestway (USA), Inc. v. Intex Mktg. Ltd.</i> , No. IPR2017-01655, 2018 WL 296084 (PTAB Jan. 4, 2018).....	13
<i>CommScope Techs. LLC v. Dali Wireless, Inc.</i> , No. IPR2022-01242, 2023 WL 2301719 (PTAB Feb. 27, 2023)	28
<i>Daiichi Sankyo Co. v. Apotex, Inc.</i> , 501 F.3d 1254 (Fed. Cir. 2007)	13
<i>Darfon Elecs. Corp. v. Shipman</i> , No. IPR2022-01008, 2022 WL 17408774 (PTAB Dec. 2, 2022).....	41

<i>Eibel Process Co. v. Minn. & Ontario Paper Co.</i> , 261 U.S. 45 (1923)	35
<i>Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.</i> , 471 F.3d 1369 (Fed. Cir. 2006)	48
<i>Ericsson Inc. v. Collision Commc'ns, Inc.</i> , No. IPR2022-01233 (PTAB Jan. 19, 2023)	23
<i>Ferring Pharms. Inc. v. Eugia Pharma Specialties Ltd.</i> , 1:22-cv-0017-MN (D. Del. May 10, 2024)	15
<i>Forest Labs., LLC v. Sigmapharm Labs., LLC</i> , 257 F. Supp. 3d 664 (D. Del. 2017)	35, 37, 48
<i>Helena Labs. Corp. v. Sebia</i> , No. IPR2024-00801, 2024 WL 4557879 (PTAB Oct. 23, 2024)	42
<i>Huawei Techs. Co., Ltd. v. WSOU Inv., LLC</i> , No. IPR2021-00225, 2021 WL 2450738 (PTAB June 14, 2021)	27
<i>In re Zurko</i> , 111 F.3d 887 (Fed. Cir. 1997)	35
<i>Int'l Bus. Machines Corp. v. Digital Doors, Inc.</i> , No. IPR2023-00970, 2024 WL 146120 (PTAB Jan. 12, 2024)	28
<i>Leo Pharm. Prods., Ltd. v. Rea</i> , 726 F.3d 1346 (Fed. Cir. 2013)	35
<i>Mylan Labs. Ltd. v. Janssen Pharmaceutica NV</i> , No. IPR2020-00440, 2020 WL 5580472 (PTAB Sept. 16, 2020)	16, 21, 27
<i>Mylan Pharms., Inc. v. Bayer Intell. Prop. GmbH</i> , No. IPR2018-01143, 2018 WL 6318139 (PTAB Dec. 3, 2018)	14
<i>NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.</i> , No. IPR2018-00752, 2018 WL 4373643 (PTAB Sept. 12, 2018)	3, 13, 17, 38
<i>Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal</i> , 868 F.3d 1013 (Fed. Cir. 2017)	10

<i>Novartis Pharms. Corp. v. Watson Labs., Inc.</i> , 611 F. App'x 988 (Fed. Cir. 2015).....	2, 35, 37, 48
<i>Opensky Indus., LLC v. VLSI Tech. LLC</i> , No. IPR2021-01064, 2022 WL 4963049 (PTAB Oct. 4, 2022)	28
<i>Padagis Israel Pharms. Ltd. v. Bausch Health Ireland Ltd.</i> , No. IPR2023-01114, 2024 WL 146121 (PTAB Jan. 12, 2024).....	48
<i>Parse Biosciences, Inc. v. 10x Genomics, Inc.</i> , No. IPR2023-01033, 2023 WL 8789872 (PTAB Dec. 19, 2023).....	41, 42
<i>PureWick Corp. v. Sage Prods., LLC</i> , 1:19-cv-1508-MN (D. Del. May 4, 2021).....	16
<i>Samsung Display Co., Ltd. v. Pictiva Displays Int'l Ltd.</i> , No. IPR2024-00855, 2024 WL 4827385 (PTAB Nov. 19, 2024)	18, 26, 29, 38
<i>Samsung Elecs. Am., Inc. v. Uniloc 2017 LLC</i> , No. IPR2019-01218, 2020 WL 103007 (PTAB Jan. 7, 2020).....	18
<i>Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC</i> , No. IPR2019-01393, 2020 WL 3273334 (PTAB June 16, 2020).....	26
<i>Siemens Mobility, Inc. v. Metrom Rail, LLC</i> , No. IPR2024-00947, 2024 WL 4827396 (PTAB Nov. 19, 2024)	45
<i>Standard Oil Co. v. Am. Cyanamid Co.</i> , 774 F.2d 448 (Fed. Cir. 1985).....	13
<i>T-Mobile USA, Inc. v. Cobblestone Wireless LLC</i> , No. IPR2024-00136, 2024 WL 2854025 (PTAB June 5, 2024).....	21
<i>T-Mobile USA, Inc. v. Wireless All., LLC</i> , No. IPR2024-00607, 2024 WL 4133856 (PTAB Sept. 10, 2024).....	21
<i>Vital Connect, Inc. v. Bardy Diagnostics, Inc.</i> , No. IPR2023-00381, 2023 WL 5059771 (PTAB July 11, 2023).....	40
Statutes	
35 U.S.C. § 314(a)	2, 3, 13, 15
35 U.S.C. § 315(e)(2).....	27

35 U.S.C. § 325(d) passim

LIST OF EXHIBITS

Exhibit No.	Description
2001	Biography of Rebecca T. Horwitz in Support of Patent Owner's Motion for Admission <i>Pro Hac Vice</i>
2002	Declaration of Rebecca T. Horwitz in Support of Patent Owner's Motion for Admission <i>Pro Hac Vice</i>
2003	Biography of Taylor Kelson in Support of Patent Owner's Motion for Admission <i>Pro Hac Vice</i>
2004	Declaration of Taylor Kelson in Support of Patent Owner's Motion for Admission <i>Pro Hac Vice</i>
2005	Biography of J. Scott Bride in Support of Patent Owner's Motion for Admission <i>Pro Hac Vice</i>
2006	Declaration of J. Scott Bride in Support of Patent Owner's Motion for Admission <i>Pro Hac Vice</i>
2007	U.S. Patent No. 10,548,846
2008	Stipulation and [Proposed] Order To Amend Scheduling Order, D.I. 159
2009	PACER Docket Report, <i>Gilead Sciences, Inc. v. Lupin Ltd. et al.</i> , No. 1:22-cv-00615-MN (D. Del.)
2010	Stipulation and Order To Amend Scheduling Order, D.I. 160
2011	Excerpt of Federal Court Management Statistics, Sep. 30, 2024
2012	Excerpt of Defendants Laurus Labs Limited, Cipla Limited, and Lupin Limited's Amended Initial Invalidity Contentions, Dec. 20, 2023
2013	Excerpt of Defendants Laurus Labs Limited, Cipla Limited, and Lupin Limited's Final Invalidity Contentions, July 2, 2024
2014	Defendants' '802 Patent Claim Chart, July 11, 2024
2015	Excerpt of Plaintiff Gilead Sciences, Inc's Final Validity Contentions, Aug. 2, 2024

Exhibit No.	Description
2016	Stipulation and Order To Amend Scheduling Order, D.I. 200
2017	Excerpt of Opening Expert Report of Prassana Jagannathan, M.D., Jan. 31, 2025
2018	Excerpt of Opening Expert Report of Jeffrey Winkler, Ph.D., Jan. 29, 2025
2019	Annotated Excerpt of Declaration of Prassana Jagannathan, M.D., Oct. 23, 2024
2020	Excerpt of Rebuttal Expert Report of David W.C. MacMillan, Ph.D. in <i>ViiV Healthcare Co. v. Gilead Sciences, Inc.</i> , 1:18-cv-00224-CFC-CJB, Jan. 10, 2020
2021	Excerpt of Hal Martin Deposition Transcript, May 2, 2024 [Confidential – Filed Under Seal]
2022	Gilead GS-9883 STR Development PDCS Group Meeting presentation, Aug. 12, 2015 [Confidential – Filed Under Seal]
2023	Annotated U.S. Patent No. 11,744,802

I. Introduction

There is no reason for the Board to spend its resources wading into the validity of U.S. Patent 11,744,802. The '802 patent, alongside three others, is the subject of a patent-infringement lawsuit in the District of Delaware that was filed nearly three years ago against Cipla and two other defendants (Lupin and Laurus). Trial is set for October 2025, long before proceedings here would conclude.

Under the Board's *Fintiv* factors, it is plain that the "efficiency and integrity of the system are best served by denying" review. *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, 2020 WL 2126495, at *3 (PTAB Mar. 20, 2020) (informative). Despite its participation in the rapidly progressing district court case, Cipla chose to wait until the very end of its one-year period to file its Petition. As a result, the parties and the district court have invested significant time and resources in the district court case. And there is complete overlap of the invalidity issues in play—the defendants in the district court (including Cipla) challenge the same claims using the same art and same experts as Cipla's Petition. The district court will have to decide these issues regardless of the Board's decision here, as Laurus and Lupin have not joined Cipla's Petition and are free to continue to pursue those defenses. The first five *Fintiv* factors plainly favor denial.

There are also significant obstacles on the merits of Cipla's Petition, relevant to the final *Fintiv* factor. The '802 patent claims tablets comprising a three-drug

combination, including 50 mg of the compound bictegravir. The Petition focuses on what was known about dosing dolutegravir, a different compound, at the '802 patent's priority date. But the Petition glosses over the fact that Gilead selected a 75 mg dose of bictegravir for its clinical trials. This is critical evidence of what a skilled artisan would have done at the time of the invention. Petitioner also outright ignores that Gilead only later selected a 50 mg dose in order to solve a problem that arose from a surprising discovery about the drug's properties. That surprise is relevant and weighs strongly against obviousness. The solution to a previously unknown problem is not obvious. *See Novartis Pharms. Corp. v. Watson Labs., Inc.*, 611 F. App'x 988, 995 (Fed. Cir. 2015) ("Even an obvious solution, however, does not render an invention obvious if the problem solved was previously unknown."). Given the Petition's failure to address critical facts relevant to an obviousness analysis, the merits are not compelling, and the *Fintiv* analysis strongly favors discretionary denial under § 314(a).

This Petition should also be denied for independent reasons under § 325(d), as the Board "defer[s] to previous Office evaluations of the evidence of record unless material error is shown." *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, No. IPR2019-01469, 2020 WL 740292, at *3 (PTAB Feb. 13, 2020) (precedential). The Petition's grounds are based on two primary references that were both considered by the examiner during prosecution, one of which (WO '323) the

examiner identified as among the “closest prior art.” Ex. 1002 at 1051. The teachings of the secondary references are also substantially the same as those previously presented. In fact, they are cumulative, as shown by Cipla’s arguments here that the two primary references alone disclose the same features as the secondary references.

Petitioner cannot show any material error to warrant the Board taking another look. Petitioner suggests only that the examiner misunderstood one of the primary references, WO ’323. The examiner did not err. Just as the examiner found, there is no specific disclosure in WO ’323 of bictegavir, emtricitabine, and tenofovir in the same tablet. And the examiner was also correct that the three-drug combination claimed in the ’802 patent produced a surprising result—that is exactly the same surprise that led Gilead to change the dose—which further weighs against invalidity.

Under either § 314(a) or § 325(d), the Board should exercise its discretion to deny Cipla’s Petition. And, as the Board has found before, the strong case for denial under either section individually leads to the inescapable conclusion that discretionary denial is the correct outcome here. *See NHK Spring Co., Ltd. v. Intriplex Techs., Inc.*, No. IPR2018-00752, 2018 WL 4373643, at *7 & n.4 (PTAB Sept. 12, 2018) (precedential).

II. Background

Gilead presents the background relevant to the *Fintiv* factors and *Advanced Bionics* framework. Should the Board institute, Gilead reserves the right to respond and dispute the background information provided in the Petition.

A. The '802 Patent

The '802 patent resulted from Gilead's work that led to Biktarvy[®], a three-drug combination of bicitgravir (BIC)¹, emtricitabine (FTC), and tenofovir alafenamide (TAF) indicated to treat HIV-1 infection.

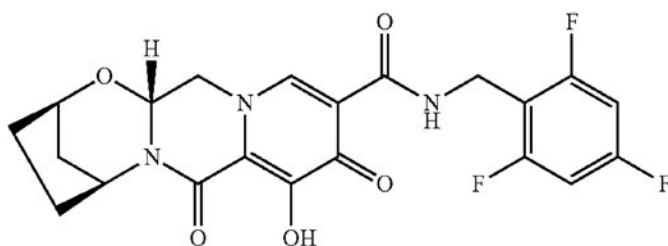
Gilead invented the integrase strand transfer inhibitor bicitgravir. During clinical trials of bicitgravir, Gilead investigated a three-drug combination to treat HIV-1. During Phase 1b and Phase 2 clinical trials, Gilead determined that the appropriate dose of bicitgravir in that three-drug combination should be 75 mg, based on human dosing studies comparing bicitgravir to 50 mg of dolutegravir. Ex. 1029; Ex. 1035. In those trials, Gilead dosed the three-drug combination as two tablets—one containing bicitgravir and a separate tablet containing emtricitabine

¹ Bicitgravir is also referred to as BIC or GS-9883, and those terms are used interchangeably. *See, e.g.*, Ex. 1029 ("Study to Evaluate Safety, Pharmacokinetics, and Antiviral Activity of Bicitgravir (GS-9883) in Human Immunodeficiency Virus (HIV)-1 Infected Participants.") (emphasis added).

and tenofovir. But when Gilead combined bictegravir, emtricitabine, and tenofovir into a single tablet, it made a surprising discovery. Clinical testing had shown that bictegravir, emtricitabine, and tenofovir have no drug interactions with each other, and so Gilead expected that the single tablet would have approximately the same bioavailability of the active ingredients as the two tablets it previously used. But that is not what happened. Instead, individuals showed about 30% higher exposure to bictegravir in the single tablet containing all three drugs, meaning the dose of bictegravir was unexpectedly higher than needed. Gilead ultimately received FDA approval for Biktarvy®, the only Gilead product on the market that contains bictegravir.

The claims of the '802 patent reflect Gilead's unexpected discovery. Claim 1 recites:

A tablet comprising 50 mg of the compound of Formula I:



or a pharmaceutically acceptable salt thereof, 25 mg tenofovir alafenamide or a pharmaceutically acceptable salt thereof, and 200 mg emtricitabine or a pharmaceutically acceptable salt thereof.

The claimed compound of Formula I is bictegrovir. The dependent claims recite limitations related to pharmaceutically acceptable salts of bictegrovir and tenofovir alafenamide, total weight of the claimed tablets, and the weight percent of bictegrovir within the claimed tablets.

The '802 patent was filed on May 6, 2022 and claims priority to provisional applications dated November 9, 2015 and September 26, 2016. The '802 patent's application was assigned for examination to Examiner Jessica Worsham. This was not the first patent concerning bictegrovir that Ms. Worsham examined. Ms. Worsham had previously examined other applications in the same family, including for U.S. Patent No. 10,548,846 (which was in prosecution for more than three years). *See* Ex. 2007 at 1.

During prosecution, Gilead submitted multiple information disclosure statements. *See, e.g.,* Ex. 1002 at 595-609. In the very first IDS, Gilead identified WO '323 and WO '351, the primary references relied on by Cipla.² *Id.* at 598. Gilead also identified other patents, articles, and information, including the product labels

² Gilead uses the Petition's nomenclature for the art asserted in each ground. WO '323 refers to WO 2014/100323 to Jin et al., and WO '351 refers to WO 2015/022351 to Renner. US '079 refers to U.S. Patent Appl. Pub. No. 2015/0231079 to Malhotra et al.

of Tivicay® and Triumeq® and publications regarding dolutegravir written by Sax and Shah. *Id.* at 604; *see also* Ex. 1022 (Tivicay® label); Ex. 1023 (Shah); Ex. 1024 (Triumeq® label); Ex. 1025 (Sax). The examiner considered each of those references. *See* Ex. 1002 at 782-794.

Following a notice of allowance, *id.* at 774-776, Gilead requested continued examination and submitted an additional IDS. *Id.* at 802, 810-813. The new IDS provided translated versions of preliminary rejections for two of Gilead's Korean patent applications. *Id.* at 813. Both of those applications concerned "a solid oral dosage form" of bictegravir, emtricitabine, and tenofovir. *Id.* at 818, 825. And in both of those rejections, the Korean patent examiner rejected the claims over the combination of WO '351 and WO '323. *Id.* Each preliminary rejection was two pages long, *id.* at 818-819, 825-826, and the examiner considered both, *id.* at 840-841. The examiner again allowed the claims. *Id.* at 832-833.

After the second notice of allowance, Gilead again requested continued examination and submitted another IDS. *Id.* at 843, 973-974. This IDS included papers from an appeal concerning a European patent to Gilead, relating to a tablet comprising bictegravir, emtricitabine, and tenofovir, in which the challengers argued that Gilead's invention was not patentable over WO '351 and WO '323. *Id.* at 847, 974. The examiner considered those papers, *id.* at 1059-1060, and allowed the claims, *id.* at 1051-1052.

The examiner's Reasons of Allowance explained that the closest art was "published after the effective filing date of the instant application and have a common assignee," and so did not qualify as prior art. *Id.* at 1051. "The next closest prior art of WO2014/100323 . . . does not teach all three drugs within the same tablet." *Id.* Additionally, the examiner acknowledged Gilead's surprising discovery, stating that "Applicants have shown a 30% higher exposure of bictegravir in a fixed dose combination of bictegravir, emtricitabine, and tenofovir alafenamide relative to its exposure when co-administered as a single agent of bictegravir with a fixed dose combination of emtricitabine and tenofovir alafenamide." *Id.* at 1051-1052.

The '802 patent issued on September 5, 2023.

B. The District Court Litigation Involving The '802 Patent Is At An Advanced Stage And Involves Three Distinct Defendants

In March 2022, Cipla, Lupin, and Laurus each notified Gilead that they were seeking FDA approval to market a generic version of Gilead's Biktarvy®. In May 2022, Gilead sued all three for patent infringement in the District of Delaware. Gilead initially asserted three patents that are listed in the Orange Book as covering Biktarvy®. Those patents are not at issue here.

Cipla became aware of Gilead's intention to assert the '802 patent more than one year before it filed its petition. After the '802 patent issued on September 5, 2023, the parties informed the district court that "by agreement of the parties,

Plaintiff [Gilead] will be filing an amended complaint against Defendants adding counts for declaratory judgment of infringement of the '802 patent.” Ex. 2008, Stipulation and [Proposed] Order to Amend Scheduling Order at 1. In October 2023, Gilead provided a courtesy draft of the amended complaint and subsequently filed the amended complaint on November 15, 2023. Ex. 2009, Civil Docket at D.I. 168.

The parties have spent substantial time and resources on fact discovery related to the '802 patent. Gilead served its initial infringement contentions for the '802 patent on November 29, 2023. *Id.* at D.I. 173. Cipla and the other defendants served initial invalidity contentions for the '802 patent on December 20, 2023. *Id.* at D.I. 184. By the time fact discovery closed on June 14, 2024, Gilead and Cipla produced over 100,000 documents based on over 100 requests for production, served and answered more than 45 interrogatories, served and answered 55 requests for admission, and completed numerous depositions.

Following final infringement contentions (July 2, 2024) and final invalidity contentions (July 11, 2024), the parties turned their attention to claim construction. Between August 9, 2024, and November 22, 2024, the parties exchanged claim terms and completed multiple rounds of briefing. *Id.* at D.I. 251, 263. The district court held a claim construction hearing on December 18, 2024 and ruled from the bench.

The parties are now in expert discovery. On January 31, 2025, Gilead served twelve opening infringement reports, and Cipla and the other defendants served six

opening invalidity reports, including from its IPR declarants Dr. Jagannathan and Dr. Winkler. The parties will serve rebuttal expert reports on March 14, 2025, and reply expert reports on April 18, 2025. Expert discovery closes on June 13, 2025.

After that, the only remaining work is trial, as the district court’s scheduling order does not allow summary judgment motions without leave of the court and limits *Daubert* motions to three-page motions submitted as part of the pre-trial order. A 5-day trial is scheduled to begin October 6, 2025.

III. Claim Construction

The Board “need only construe terms that are in controversy, and only to the extent necessary to resolve the controversy.” *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Petitioner appears to seek construction of the term “a pharmaceutically acceptable salt thereof.” *See* Petition at 31. Gilead does not believe the Board needs to construe this term to resolve the controversy by denying the Petition. Gilead reserves the right to propose an alternative construction should the Board institute trial.³

³ For instance, Petitioner’s construction is at minimum incomplete, as it appears to suggest a meaning for how much of a salt to use, rather than what a skilled artisan would consider to constitute a pharmaceutically acceptable salt.

IV. Level Of Ordinary Skill In The Art

Gilead believes that a person of ordinary skill in the art in the field of the '802 patent would be a person or team of persons working as part of a multi-disciplinary drug development team with an advanced degree or degrees (such as a Ph.D. and/or M.D.) in the relevant fields, which could include chemistry (for example, organic, synthetic, computational, pharmaceutical, or medicinal chemistry), biochemistry, biology, medicine, pharmacology, pharmaceuticals, and/or pharmaceutical sciences. This person or team of persons would have at least two years of practical experience in one or more of these relevant fields. This person(s) could also be someone with a lower degree level (e.g., a master's (M.S.) degree) in one of these disciplines, but with greater practical experience (e.g., at least four years in the case of a person with a M.S. degree). As needed in the course of the drug development process, this team would include persons of skill possessing combinations of these relevant qualifications as well as other people with whom the persons of ordinary skill in the art may consult.

A person or team of persons of ordinary skill in the art of the '802 patent would have training and experience in medicine, pharmacology, pharmaceuticals, and/or pharmaceutical sciences, including training and experience in the development of dosages and formulations for pharmaceutical products for the treatment of human patients.

As needed in the course of developing, formulating, testing, and administering a pharmaceutical product (including the active pharmaceutical ingredients therein), the person of skill would consult with a team which would include persons of skill possessing combinations of these relevant qualifications as well as other people with whom the persons of ordinary skill in the art may consult.

Unlike Gilead's definition, Petitioner's definition of a person of ordinary skill in the art requires that person to be "particularly aware of the financial impact of developing a single tablet ART regimen desired by physicians prior to the Effective Date," and Petitioner supports its definition by relying on Gilead SEC filings. *See* Petition at 30. "Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (internal quotation marks omitted). Awareness of a drug's potential financial impact or statements in an SEC filing are none of those things. Rather, Cipla's definition improperly seeks to infuse its argument for the supposed *motivation* to achieve the invention here into the definition of a POSA. *See Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) ("A person of ordinary skill in the art is also presumed to be

one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate”).

Gilead asks the Board to adopt its proposal for the level of skill in the art. However, the Board should exercise its discretion to deny the Petition under either party’s proposed definition of a skilled artisan, as explained below.

V. The Board Should Exercise Its Discretion To Deny This Petition Under § 314(a)

Petitioner’s entire *Fintiv* analysis is one paragraph. That is striking. The facts here are remarkably similar to both *Fintiv* and *NHK*, but Petitioner makes little attempt to justify why the outcome should not be the same. It is Petitioner’s burden to show that institution is proper, not Patent Owner’s burden to establish the opposite. *See, e.g., Bestway (USA), Inc. v. Intex Mktg. Ltd.*, No. IPR2017-01655, 2018 WL 296084, at *5 (PTAB Jan. 4, 2018) (denying institution under § 314(a) because Petitioner “does not persuade us that institution . . . is appropriate”). Cipla’s single, cursory paragraph is not enough.

Regardless, the *Fintiv* factors strongly favor denying this Petition. The district court case involving the ’802 patent is well underway and scheduled for trial in early October 2025, more than six months before the statutory deadline for a final written decision. Cipla raises the same references to challenge the same claims in the district court, and two other defendants—who have not joined Cipla’s Petition—sponsor the same challenges in the district court. “Given the advanced stage of the copending

district court case and the extensive overlap of the asserted prior art, expert testimony, and claim construction, [] it would be an inefficient use of Board resources to proceed with this *inter partes* review in parallel with the district court case.” *Mylan Pharms., Inc. v. Bayer Intell. Prop. GmbH*, No. IPR2018-01143, 2018 WL 6318139, at *6 (PTAB Dec. 3, 2018).

Nor are the merits of the Petition compelling. Before the priority date of the ’802 patent, Gilead selected a 75 mg dose of bicitgravir for its Phase 2 clinical trials. *See* Petition at 17 (citing Ex. 1035). But the Petition’s obviousness analysis under all three grounds effectively ignores that fact. Additionally, Gilead only moved away from the 75 mg dose due to a problem that was not known as of the priority date. Other facts and circumstances likewise weigh in favor of denial, including that the Petition is based on “the same or substantially the same prior art or arguments previously [that] were presented to the Office.” 35 U.S.C. § 325(d).

For these reasons, the Board should exercise its discretion to deny this Petition under § 314(a).

A. Factor 1 Favors Denial: The District Court Is Not Likely To Grant A Stay

The first *Fintiv* factor requires consideration of whether the district court has stayed or may stay the proceeding pending inter partes review. “A district court stay of the litigation pending resolution of the PTAB trial allays concerns about inefficiency and duplication of efforts.” *Fintiv*, 2020 WL 2126495, at *3.

The district court has not entered a stay in this case, and it is telling that Cipla has not requested one. That's because even if requested, the district court is highly unlikely to grant a stay. The case has been pending for nearly three years and has progressed significantly, as discussed more below. The likelihood of stay worsens with each passing day. In the three months since the filing of the Petition, the parties have exchanged opening expert reports and continue to work on additional expert discovery. And this IPR is unlikely to simplify the district court proceeding, including because there are two other defendants and three other patents at issue. Either of those facts alone is reason enough to deny a stay, as the district judge in the co-pending district court case has previously found. *See, e.g., Ferring Pharms. Inc. v. Eugia Pharma Specialties Ltd.*, 1:22-cv-0017-MN, D.I. 139 (D. Del. May 10, 2024) (denying stay where “[t]here are currently other Defendants involved in the trial scheduled to take place”); *PureWick Corp. v. Sage Prods., LLC*, 1:19-cv-1508-MN (D. Del. May 4, 2021) (denying partial motion to stay case where IPR was instituted on one patent and three patents were not the subject of IPRs).

Given that the district court is unlikely to stay this advanced case, this factor favors denial. *See Mylan Labs. Ltd. v. Janssen Pharmaceutica NV*, No. IPR2020-00440, 2020 WL 5580472, at *5-6 (PTAB Sept. 16, 2020) (“We consequently conclude that the balance of facts in the two litigations indicate that no stay is likely

to be entered in either, and therefore *Fintiv* factor 1 leans towards denial of institution.”).⁴

B. Factor 2 Favors Denial: The District Court’s Trial Date Is Six Months Before The Projected Statutory Deadline For The PTAB’s Final Written Decision

Fintiv Factor 2 considers the proximity of the district court’s trial date to the Board’s projected statutory deadline for a final written decision. Under the second factor, “[i]f the [district] court’s trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution.” *Fintiv*, 2020 WL 2126495, at *4. Here, trial is scheduled in the district court six months before the projected statutory deadline.

The district court case involving the ’802 patent has been pending since May 9, 2022. Trial is scheduled for October 6, 2025. Ex. 2010, Stipulation and Order to Amend Scheduling Order at 4. There is no reason to believe that the trial date will move significantly, if at all, given that the scheduled trial date is already nine months later than the median time to trial in the District of Delaware, and the parties are well on track to satisfy the current schedule. *See* Ex. 2011, September 30, 2024 Federal

⁴ Even if the Board declines to speculate how the district court may rule on a motion to stay, this factor would at worst be neutral. *See Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, 2020 WL 2486683, at *5 (PTAB May 13, 2020).

Court Management Statistics at 2 (median time to trial in the District of Delaware is currently 32.2 months). Using that median time, a trial in this case would be predicted to occur in January 2025, which is earlier than the scheduled trial date and more than sixteen months before any expected final written decision. *See* June 21, 2022, Director’s Guidance Memorandum at 3 (directing the Board to “consider the median time from filing to disposition of the civil trial for the district in which the parallel litigation resides”).

If institution is granted, the projected statutory deadline for the Board’s final written decision would be in May 2026. This timing—a district court trial six months before the Board’s final determination—favors denial. *See NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc.*, No. IPR2018-00752, 2018 WL 4373643, at *7 (PTAB Sept. 12, 2018) (precedential) (denying institution where trial was scheduled six months before expected final written decision); *see also Samsung Elecs. Am., Inc. v. Uniloc 2017 LLC*, No. IPR2019-01218, 2020 WL 103007, at *4 (PTAB Jan. 7, 2020) (factor weighs in favor of denying institution where jury selection was scheduled for approximately six months before trial in the Board proceeding would conclude). Indeed, even shorter times between trial and projected final determination favor denial. *See, e.g., AT&T Servs. Inc. v. Asus Tech. Licensing Inc.*, No. IPR2024-00992, 2024 WL 5126018, at *5 (PTAB Dec. 16, 2024) (“trial in the parallel district court proceedings [scheduled] to begin four to five months prior to the deadline for our

final written decision . . . weighs substantially in favor of discretionary denial”); *Samsung Display Co., Ltd. v. Pictiva Displays Int’l Ltd.*, No. IPR2024-00855, 2024 WL 4827385, at *3 (PTAB Nov. 19, 2024) (trial “scheduled to take place ‘more than three months before the projected statutory deadline’ . . . favors denial”); *Fintiv*, 2020 WL 2486683, at *5 (“Because the currently scheduled District Court trial is scheduled to begin two months before our deadline to reach a final decision, this factor weighs somewhat in favor of discretionary denial in this case.”).

Fintiv Factor 2 clearly weighs in favor of denying this Petition.

C. Factor 3 Favors Denial: The District Court And The Parties Have Significantly Invested In The District Court Proceeding

Fintiv Factor 3 considers investment in the parallel proceeding by the district court and the parties. This factor analyzes “the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision.” *Fintiv*, 2020 WL 2126495, at *4. Where, like here, the parallel district court case is very advanced, this factor weighs strongly in favor of denial. *See id.*

The parties have spent considerable time and resources in the district court case. By the time the Board decides whether to institute this Petition, the parties will have completed the following:

- Fact discovery completed on June 14, 2024, including 5 fact depositions of Gilead witnesses, 3 fact depositions of Cipla witnesses, 40 requests for production served by Cipla, 77 requests for production served by Gilead, 73,696 documents and 104,680 pages produced by Gilead, 36,857 documents and 606,070 pages produced by Cipla, 26 interrogatories served by Cipla, 20 interrogatories served by Gilead, 17 requests for admission served by Cipla, and 38 requests for admission served by Gilead.
- Gilead served initial infringement contentions for the '802 patent on November 29, 2023. Ex. 2009 at D.I. 173.
- Cipla served initial invalidity contentions for the '802 patent on December 20, 2023. Ex. 2012.
- Gilead served final infringement contentions on July 2, 2024. Ex. 2009 at D.I. 239.
- Cipla served final invalidity contentions for the '802 patent on July 2, 2024, Ex. 2013, and a final invalidity contention claim chart on July 11, 2024, Ex. 2014.
- Gilead served final validity contentions on August 2, 2024. Ex. 2015.
- Cipla served final non-infringement contentions on August 2, 2024. Ex. 2009 at D.I. 246.

- The parties completed claim construction briefing on November 22, 2024. *Id.* at D.I. 263. The district court held a *Markman* hearing on December 18, 2024, where the court resolved the parties' disputes in a ruling from the bench.
- The parties served 18 total opening expert reports on January 31, 2025, including six related to the '802 patent.
- The parties will serve rebuttal expert reports on March 14, 2025, and reply expert reports on April 18, 2025.

Additionally, Gilead expects that the parties will have completed a significant portion of the expert depositions before any institution decision as expert discovery closes shortly after the expected decision on institution. In this case, it is unlikely that the parties will file any motions for summary judgment, as case dispositive motions are not permitted without leave of the court. And the parties are not permitted to file any *Daubert* motions and instead can make a challenge to expert disclosures in a three-page motion. Ex. 2016, Stipulation and Order to Amend Scheduling Order at 4. In short, this case will be close to trial-ready by the time of the institution decision. *See Mylan*, 2020 WL 5580472, at *7.

The parties' significant work and investment in the district court litigation favors denying institution. *See, e.g., T-Mobile USA, Inc. v. Wireless All., LLC*, No. IPR2024-00607, 2024 WL 4133856, at *5 (PTAB Sept. 10, 2024) (factor favors

denying institution where “parties have already invested heavily in the litigations, including serving infringement and invalidity contentions, filing discovery motions, completing fact discovery, and serving opening expert reports,” because “work by the parties and the district court is at an advanced stage”); *T-Mobile USA, Inc. v. Cobblestone Wireless LLC*, No. IPR2024-00136, 2024 WL 2854025, at *7 (PTAB June 5, 2024) (“Because the *Markman* hearing will be completed prior to the time of the institution decision and discovery will have proceeded to an advanced stage (including the close of fact discovery and exchange of opening and rebuttal expert reports) by the time of this Decision, we find that factor 3 weighs in favor of exercising discretion to deny institution.”). Indeed, the district court case is further advanced than other cases in which the Board has exercised its discretion to deny institution. *See, e.g., 10x Genomics, Inc. v. President & Fellows of Harvard Coll.*, No. IPR2023-01299, 2024 WL 993828, at *8 (PTAB Mar. 7, 2024) (parties had “exchanged initial and supplemental infringement and invalidity contentions, completed claim construction briefing and held a claim construction hearing” but were still in fact discovery).

On top of the considerable resources the parties have expended on the district court case, the district court itself has also invested time and resources in the case. The district court held a *Markman* hearing on December 18, 2024, and ruled from the bench on the parties’ disputes. Ex. 2009 at Dec. 18, 2024 Minute Entry. And

during fact discovery, the district court resolved a discovery dispute. *Id.* at D.I. 89. The district court’s investment weighs in favor of denying this Petition. *See 10x Genomics, Inc. v. President & Fellows of Harvard Coll.*, No. IPR2023-01299, 2024 WL 993828, at *8 (PTAB Mar. 7, 2024) (“Even more significantly, the district court has invested substantial resources in the parallel proceeding. The district court has held a claim construction hearing and issued its Claim Construction Order on February 1, 2024.”).

Cipla’s delay in filing this Petition further supports denial. The Board has warned that “notwithstanding that a defendant has one year to file a petition, it may impose unfair costs to a patent owner if the petitioner, faced with the prospect of a looming trial date, waits until the district court trial has progressed significantly before filing a petition at the Office.” *Fintiv*, 2020 WL 2126495, at *5. But that’s exactly what Cipla did. After it learned that Gilead would assert the ’802 patent, Cipla waited more than a year to file its Petition.

The ’802 patent issued on September 5, 2023, and on October 4, 2023, Gilead and Cipla informed the district court that “by agreement of the parties,” Gilead would assert the ’802 patent in the district court litigation. Ex. 2008 at 1. Gilead provided a courtesy draft of the amended complaint on October 20, 2023, and then filed the amended complaint to assert the ’802 patent on November 15, 2023. Ex. 2009 at D.I. 168. Gilead served its initial infringement contentions for the ’802

patent two weeks later. *Id.* at D.I. 173. Just weeks after that, Cipla served initial invalidity contentions for the '802 patent. *Id.* at D.I. 184. But Cipla did not file its Petition then. Seven months later, Cipla served final invalidity contentions for the '802 patent. Cipla didn't file its Petition then either. Cipla waited until October 28, 2024, about two weeks before its statutory deadline to file the Petition—all while the district court case continued moving forward.

The Board has found shorter delays than this favoring denial. *See, e.g., 10x Genomics,* , 2024 WL 993828, at *8 (“[T]he fact that Petitioner waited to file its Petition until exactly one year after it was served with the counterclaim for infringement of the '303 Patent and nine months after receiving the initial infringement contentions weighs in favor of exercising our discretion to deny institution.”); *Ericsson Inc. v. Collision Commc'ns, Inc.*, No. IPR2022-01233, Paper 12 at 14-15 (PTAB Jan. 19, 2023) (factor weighs in favor of discretionary denial where the petition was filed almost one year from the filing of the district court complaint and almost nine months after receiving infringement contentions).

Fintiv Factor 3 clearly weighs in favor of denying this Petition.

D. Factor 4 Favors Denial: The Same Claims, Grounds, Arguments, And Evidence Are At Issue In The Petition And In The Parallel Proceeding

The fourth *Fintiv* factor, overlap between issues raised in the Petition and in the parallel proceeding, considers “inefficiency and the possibility of conflicting

decisions.” *Fintiv*, 2020 WL 2126495, at *5. Therefore, “if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial.” *Id.* There is complete overlap here: the same issues and the same prior art concerning the same claims of the ’802 patent will have to be decided by the district court.

Cipla’s Petition relies on five references for its obviousness challenges: WO ’323, WO ’351, US ’079, Bowker, and Paulekuhn. Cipla and the other defendants rely on each of those references in the district court too. Each reference is summarized and discussed in detail in Cipla’s and the other defendants’ final obviousness contentions. Ex. 2013 at 4 (Paulekuhn), 6 (Bowker), 9 (WO ’323), 11 & n.6 (WO ’351), 15 (US ’079), 36-50 (WO ’323 and WO ’351), 55 (US ’079), 65 (Bowker), 66 (Paulekuhn); *see also generally* Ex. 2014, ’802 patent Claim Chart. Indeed, Cipla and the other defendants contend that the claims of the ’802 patent would have been obvious in light of certain “exemplary combinations,” including “US ’356 (or WO ’323) + WO ’351 (or US ’332) + the knowledge of one of ordinary skill in the art.” *Id.* at 482-484 (emphasis added).

The opening expert reports served by Cipla and the other defendants further demonstrate the overlap between the validity issues here and in the district court. Like in the Petition, Cipla and the other defendants raise three invalidity grounds in the district court—obviousness in light of the combination of (1) WO ’323 and WO

'351, (2) WO '323, WO '351, Bowker, and Paulekuhn, and (3) WO '323, WO '351, and US '079. Ex. 2017, Jagannathan Opening Report at 3, 56-88. Dr. Jagannathan and Dr. Winkler, Cipla's IPR declarants, also issued opening expert reports in the district court challenging the '802 patent. Ex. 2017; Ex. 2018, Winkler Opening Report. Indeed, Dr. Jagannathan's district court analysis copies nearly verbatim his IPR declaration. *See, e.g.*, Ex. 2019, Jagannathan IPR Declaration Comparison (claim 1 analysis highlighted to show language that is identical in Ex. 2017 at 70-76).

Additionally, both the district court and the Board will need to determine the validity of every claim of the '802 patent. All 13 issued claims are currently asserted in the district court. Cipla's final invalidity contentions challenge all 13 issued claims. Cipla's expert report on invalidity challenges all 13 issued claims. Ex. 2017 at 70-88. And here, Cipla's Petition challenges all 13 issued claims. There is complete overlap of the claims at issue.

Accordingly, "the Petition is based on the same prior art references, presently asserted against the same patent claims, as the District Court action, raising the specter of significant overlap and duplication of efforts." *Samsung Display*, 2024 WL 4827385, at *5. This too weighs strongly in favor of denial.

Nor is this Petition a "true alternative" to district court litigation. *Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC*, No. IPR2019-01393, 2020 WL 3273334, at *5 (PTAB June 16, 2020) (informative). The district

court will have to resolve these same issues regardless of the outcome before the Board because two other defendants (Lupin and Laurus) in the district court action are raising the same invalidity defenses. For that reason, Cipla cannot avoid inefficient, duplicative efforts between the district court and the Board through a stipulation. Indeed, Cipla has not even offered a *Sotera* stipulation. In any event, a *Sotera* stipulation from Cipla would be effectively meaningless here. Laurus and Lupin can maintain the invalidity challenges that the defendants have jointly put forth—including all of those based on the references relied on in the Petition.

Fintiv Factor 4 clearly weighs in favor of denying this Petition.

E. Factor 5 Favors Denial: Cipla Is The Petitioner And A Defendant In The District Court

Petitioner Cipla is a defendant in the district court litigation. “Because the petitioner and the defendant in the parallel proceeding are the same party, this factor weighs in favor of discretionary denial.” *Fintiv*, 2020 WL 2486683, at *6. Cipla “will have the opportunity to fully litigate the invalidity” of the ’802 patent in the district court case, “which is already well underway.” *Mylan*, 2020 WL 5580472, at *10.

That there are two additional defendants involved in the district court not related to Cipla weighs even more strongly against instituting this Petition. Factor 5 relates to estoppel under § 315(e)(2), as this factor favors institution when the Board’s final written decision is expected to simplify district court proceedings. *See*

Huawei Techs. Co., Ltd. v. WSOU Inv., LLC, No. IPR2021-00225, 2021 WL 2450738, at *6 (PTAB June 14, 2021). Here, Defendants Laurus and Lupin would not be bound by any estoppel provisions. Neither joined Cipla’s Petition, and neither are disclosed by Cipla to be real parties in interest. Thus, as with Factor 4, Laurus and Lupin would be free to continue to raise these same challenges in the district court regardless of the result here.

Fintiv Factor 5 weighs in favor of denying this Petition.

F. Factor 6 Favors Denial: The Petition Does Not Present A Compelling Case Of Unpatentability

The sixth *Fintiv* Factor accounts for other circumstances that may impact the Board’s exercise of discretion, including whether the Petitioner has presented a “compelling, meritorious challenge.” *CommScope Techs. LLC v. Dali Wireless, Inc.*, No. IPR2022-01242, 2023 WL 2301719, at *3 (PTAB Feb. 27, 2023) (precedential). Cipla cannot meet that standard.

“Compelling, meritorious challenges are those in which the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence.” June 21, 2022 Guidance Memorandum at 4; *see also Int’l Bus. Machines Corp. v. Digital Doors, Inc.*, No. IPR2023-00970, 2024 WL 146120, at *13 (PTAB Jan. 12, 2024) (“Patent Owner has raised substantial issues with Petitioner’s analysis of the challenged independent claims, so that the evidence does not plainly support Petitioner’s position.”). “[T]he

compelling merits standard is a higher standard than the standard for institution set by statute.” *CommScope*, 2023 WL 2301719, at *1. A challenge can only meet this standard “if it is highly likely that the petitioner would prevail with respect to at least one challenged claim.” *Opensky Indus., LLC v. VLSI Tech. LLC*, No. IPR2021-01064, 2022 WL 4963049, at *20 (PTAB Oct. 4, 2022) (precedential).

Where there is a “genuinely-disputed issue” relevant to the patentability challenge, “[t]hat genuine dispute . . . casts doubt upon whether Petitioner ‘is highly likely’ to prevail.” *Samsung Display*, 2024 WL 4827385, at *6; *see also AT&T Servs. Inc. v. ASUS Tech. Licensing Inc.*, No. IPR2024-00992, 2024 WL 5126018, at *7 (PTAB Dec. 16, 2024) (“the Petition and the preliminary evidence do not present a compelling, meritorious challenge because there are genuinely disputed issues as to whether [prior art] teaches the final limitations of independent claims 1 and 12”). Petitioner cannot meet the compelling-merits standard where the Patent Owner points out that Petitioner’s case “is a close call.” *Fintiv*, 2020 WL 2486683, at *7.

The Petition simply does not show that Cipla is “highly likely to prevail” on any challenged claim. Instead of presenting a compelling, meritorious challenge, Cipla recycles prior art already considered and rejected by the examiner and ignores undisputed evidence showing that even Gilead did not initially select a 50 mg dose of bictegavir. Additional “facts and circumstances,” including the district court’s

unique access to additional highly relevant evidence and Petition’s reliance on same or substantially the same art as was before the examiner also favor denial under the sixth *Fintiv* factor. *Fintiv*, 2020 WL 2126495, at *7.

1. The Merits Of The Petition Are Not Compelling

Independent claim 1 requires “50 mg of the compound” bicitegravir, and that limitation is a requirement of every challenged claim. Among other reasons why the Petition’s merits are not compelling, the selection of 50 mg would not have been obvious. To begin with, Petitioner’s combination of WO ’323 and WO ’351 (with or without the additional secondary references added to Grounds 2 and 3) “does not specifically disclose or exemplify a single tablet specifically containing 50 mg of compound 42 (BIC).” Ex. 1003 at ¶ 186. A skilled artisan would not have selected the required 50 mg given the available art pointing towards a 75 mg dose.

a. A Skilled Artisan Would Not Have Selected 50 Milligrams Of Bicitegravir Based On Dolutegravir

The Petition focuses significant energy on what was known about dosing dolutegravir—a different compound—in November 2015 (the ’802 patent’s priority date) while conveniently ignoring actual bicitegravir dosing decisions made by Gilead around the same time.

By 2015, Gilead had started clinical trials with bicitegravir. For example, Petitioner and its expert describe a Phase 1b study on bicitegravir published by Gilead

on February 6, 2015. *See* Petition at 17; Ex. 1003 at ¶ 94 (citing Ex. 1029). In that Phase 1b study, Gilead studied the safety, pharmacokinetics, and antiviral activity of bicitgravir in HIV-1 infected subjects. *See* Ex. 1029 at 4. The study design included four cohorts, each with different dosages, including 5 mg, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg. *Id.* at 7-8; *see also* Petition at 17 (“Another example available to the POSA was a clinical protocol studying Gilead’s compound ‘GS-9883’ in HIV-1 infected patients at once-daily doses of 5, 10, 25, 50, and 100 mg.”) (conspicuously omitting the 75 mg experimental dose).

In March 2015, based on the results the Phase 1b dosing study, Gilead selected 75 mg of bicitgravir as the appropriate dose for Phase 2 studies. Petitioner acknowledges that “[i]n a later Phase 2 protocol, 75 mg of GS-9883 was selected as the experimental dose, to be given in combination with 25 mg TAF and 200 mg FTC.” Petition at 17. Petitioner’s expert agrees. Ex. 1003 at ¶ 95 (citing Ex. 1035).

Petitioner’s expert contends that a skilled artisan would have selected bicitgravir from WO ’323 and then “would have considered and tested dosages in WO ’323 such as 25 mg, 50 mg, and 100 mg.” *Id.* at ¶ 175. But Petitioner ignores that Gilead actually did a wise dose-ranging study (from 5 mg to 100 mg). Based on that testing, Gilead determined that 75 mg of bicitgravir was the appropriate dose. Gilead published its selection of a 75 mg dose in its Phase 2 study protocol. *See* Ex. 1035.

Petitioner throws overboard the real-world evidence of the 75 mg dosing of bictegravir in lieu of speculative 50 mg dosing based on a different molecule, dolutegravir. *See, e.g.*, Petition at 55 (justifying a 50 mg dose of bictegravir because, according to its expert, “DTG and BIC would have expectedly shared biological properties due to their structural similarity”). But Gilead’s Phase 2 study specifically compared the safety and efficacy of bictegravir to dolutegravir. *See* Ex. 1035. As Gilead summarized, the purpose of the study was to “evaluate the efficacy, safety and tolerability of GS-9883 [bictegravir] + emtricitabine/tenofovir alafenamide (FTC/TAF) fixed dose combination (FDC) versus dolutegravir (DTG) + FTC/TAF in HIV-1 Infected, antiretroviral treatment-naive adults.” *Id.* at 2 (emphasis added). The experimental treatment arm used a “75 mg tablet” of bictegravir “administered orally.” *Id.* at 3. The “active comparator” treatment arm used “Dolutegravir (DTG) 50 mg tablet administered orally.” *Id.* In other words, Gilead—the company actively developing the drug with the most information and knowledge about its anti-viral activity and efficacy—determined that 75 mg of bictegravir was the appropriate dose to compare to 50 mg of dolutegravir.

Petitioner’s expert Dr. Winkler submitted a 74-page declaration describing purported similarities between bictegravir and dolutegravir but does not grapple with, or even cite, this clinical study. This omission is critical. The Phase 2 protocol demonstrates that a skilled artisan would *not* have used the same dose of bictegravir

as dolutegravir, despite whatever similarities may exist between those two compounds. And a difference in appropriate dosing between these two compounds is not all that surprising—bictegravir is substantially different from dolutegravir, including because bictegravir includes a bridged ring system, a different number of fluorine substituents, a different orientation of fluorine substituents, and different stereochemistry, all of which contribute to significant changes in sterics, electronics, conformation, volume, globularity, spatial orientation, number of stereocenters, lipophilicity, and more. *See* Ex. 2020, MacMillan Rebuttal Expert Report (*ViiV v. Gilead*) at 5-15, 18-25. As Petitioner’s materials explain, “even small bioisosteric changes can have a dramatic impact on the physicochemical and biochemical properties of a compound.” Ex. 1047-B at 235. That is why every potential drug compound goes through a series of rigorous testing during development and why the typical drug development process involves screening hundreds of thousands of compounds and performing pre-clinical and clinical testing on hundreds to result in a single new drug. *See* Ex. 1047-A at 7 (explaining drug discovery and development process). The differences between bictegravir and dolutegravir are far more than “small bioisosteric changes.”

In short, contrary to Petitioner’s contention, all publicly available information and real-world evidence indicate that a skilled artisan would not have selected a 50 mg dose of bictegravir at the priority date. The short shrift Petitioner gives to that

evidence casts significant doubt on Petitioner's ability to prevail, making this is far from a compelling challenge.

b. Gilead's Solution To An Unexpected And Surprising Problem Was Not Obvious

The Petition likewise has little discussion of *why* Gilead ultimately selected 50 mg of bictegravir, rather than the 75 mg dose used in its Phase 2 studies. But the '802 patent is not silent on that. The '802 patent explains the reason for the dose change—Gilead discovered a previously unknown problem with bictegravir:

The total exposure of the compound of Formula I [bictegravir], under fasted conditions, was approximately 30% higher when dosed in the bilayer tablet formulation F2, containing two additional therapeutic agents (TAF and FTC), compared to single agent tablet formulation F1, co-dosed with a fixed dose combination tablet containing TAF and FTC (F3). . . . Based on the data from this study, a new fixed dose formulation of the compound of Formula I, emtricitabine, and tenofovir alafenamide was developed.

Ex. 1001 at 61:24-42. That is, combining bictegravir, emtricitabine, and tenofovir alafenamide into a single tablet resulted in a significantly higher bictegravir exposure than was expected, leading to unknown and possibly deleterious effects on

patients. It is of no moment whether the *solution* to this problem (i.e., the 50 mg dose) was obvious once the problem was known, because the *problem itself* was unrecognized in the art at the priority date of the '802 patent.

“[S]olving an unrecognized problem in the art can itself be a[] nonobvious patentable invention, even where the solution is obvious once the problem is known.” *Forest Labs., LLC v. Sigmapharm Labs., LLC*, 257 F. Supp. 3d 664, 686 (D. Del. 2017), *aff’d* in relevant part, 918 F.3d 928, 935 (Fed. Cir. 2019) (citing *Eibel Process Co. v. Minn. & Ontario Paper Co.*, 261 U.S. 45, 68 (1923)); *see also Novartis*, 611 F. App’x at 995 (“Even an obvious solution, however, does not render an invention obvious if the problem solved was previously unknown.”); *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1353 (Fed. Cir. 2013) (“an invention can often be the recognition of a problem itself”); *In re Zurko*, 111 F.3d 887, 890 (Fed. Cir. 1997) (“[T]o say that the missing step comes from the nature of the problem to be solved begs the question because the Board has failed to show that this problem had been previously identified anywhere in the prior art.”).

Gilead discovered—and then solved—a previously unknown problem here. The increase in bicitgravir exposure reported in the '802 patent was a surprise. Dr. Hal Martin, who was a Director at Gilead involved in the bicitgravir clinical trials, testified in the district court litigation that Gilead had previously “[REDACTED]” between bicitgravir, emtricitabine, and tenofovir

alafenamide. Ex. 2021, Martin Tr. at 199:5-17; *see also id.* at 91:2-5 (“[REDACTED]”), 189:8-16 (“[REDACTED]”). Accordingly, Gilead expected that a single-tablet regimen would have close to the same bioavailability as giving bicitgravir in a separate tablet from emtricitabine (FTC) and tenofovir alafenamide (TAF). *Id.* at 195:18-196:24.

When Gilead performed relative bioavailability studies, the results were “totally unexpected.” *Id.* at 199:5-17. Those studies showed, as reported in the ’802 patent, a “[REDACTED]” *Id.* It was only upon discovering this “totally unexpected” increase in exposure that Gilead changed the bicitgravir dose. *Id.* at 91:12-24 (“[REDACTED]”), 199:18-200:7.

Gilead’s ultimate selection of a 50 mg dose was not driven by the known dolutegravir dose. Rather, it was driven by an unexpected and previously unrecognized problem—a 30% increase in bictegravir exposure when bictegravir, emtricitabine, and tenofovir alafenamide were formulated in a single tablet. *See id.* at 200:8-15 (“[REDACTED]

[REDACTED]”); *see also id.* at 200:20-25 [REDACTED]

[REDACTED]”). The problem of a 30% increase in exposure was not known as of the priority date, so Gilead’s solution for that unknown problem would not have been obvious. *See, e.g., Novartis*, 611 F. App’x at 995; *Forest Labs.*, 257 F. Supp. 3d at 686.

2. The District Court Is Better Suited To Evaluate The Issues Here Because Of Additional Highly Relevant Evidence Before That Court

On top of the fact that Petitioners have not presented a compelling challenge, additional “facts and circumstances” weigh in favor of discretion denial. *See Fintiv*, 2020 WL 2126495, at *7. Specifically, Gilead’s response to Petitioner’s obviousness challenges relies on fact testimony from witnesses involved in Gilead’s clinical trials, such as Dr. Martin (discussed above) and others. Those witnesses have been

deposed in connection with the district court litigation. Similarly, numerous documents produced in the district court litigation demonstrate that the work performed by Gilead following the surprising discovery of bictegravir's 30% higher exposure was not trivial. *See, e.g.*, Ex. 2022. Those witnesses and documents bear directly on the obviousness questions implicated both here and in the district court. But the district court is uniquely situated to evaluate the credibility of those witnesses, who are expected to testify either live or by deposition at trial regarding the discovery of the 30% increase in exposure and the work that resulted from that discovery. *See Samsung Display*, 2024 WL 4827385, at *8 (Factor 6 favors denial because the issues “may be better suited for resolution by the District Court, where live testimony is the norm . . . and live witness testimony may be a particularly effective tool for fleshing out those credibility issues”). Additionally, Dr. Jagannathan's district court opinions for the '802 patent incorporate and rely on an additional expert who is not an IPR declarant, which further indicates that the district court will have the benefit of assessing these same issues with a fuller record. *See* Ex. 2017 at ¶ 10.

3. The Examiner Considered The Art And Teachings Of Petitioner's Grounds

Finally, the Board should exercise its discretion to deny this Petition because the art Petitioner relies on is the same or substantially the same as the art that was before the examiner. *See NHK*, 2018 WL 4373643, at *7 & n.4. As discussed further

below, WO '323 and WO '351 were considered by the examiner, and the teachings Petitioner pulls from the secondary references were also before the examiner. There is no need for the Board to re-do the work of the examiner, especially where the district court will already be addressing the invalidity issues posed in the Petition.

VI. The Board Should Exercise Its Discretion To Deny This Petition Under § 325(d)

“In determining whether to institute or order [an *inter partes* review], the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). The Board applies a two-part framework to consider whether to exercise discretion to deny institution under § 325(d): “(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics*, 2020 WL 740292, at *3. “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.*

The primary references, WO '323 and WO '351, were indisputably considered by the examiner. The secondary references are all cumulative, an analysis

that the Petition does not even attempt to undertake. And the examiner made no error in considering the teachings of WO '323. The Board should exercise its discretion to deny this Petition under § 325(d).

A. *Advanced Bionics* Part 1: The Same Or Substantially The Same Prior Art Was Previously Presented To The Patent Office

The first part of the *Advanced Bionics* framework examines “whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office.” *Advanced Bionics*, 2020 WL 740292, at *3. “Previously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.” *Id.* The Petition’s references were all before the examiner or are substantially the same as art before the examiner.

There is no dispute that WO '323 and WO '351 were previously considered by the Office. The examiner discussed WO '323 as “the next closest prior art” in the Notice of Allowance. Ex. 1002 at 1051. Additionally, both WO '323 and WO '351 were listed in an IDS and appear on the face on the '802 patent. *See* Ex. 1002 at 783 (listing WO '323 and WO '351), 794 (examiner acknowledging she considered all citations not crossed out); Ex. 2023, Annotated '802 patent at 2; *see also Vital Connect, Inc. v. Bardy Diagnostics, Inc.*, No. IPR2023-00381, 2023 WL 5059771,

at *5 (PTAB July 11, 2023) (“There can be no dispute that Oster was before the Office. Oster was listed in an information disclosure statement (IDS) and appears on the face of the ’743 patent.”). As even Petitioner concedes, this factor is plainly met for the Petition’s primary obviousness references. *See* Petition at 32.

This factor is also met for the secondary references—Paulekuhn, Bowker, and US ’079. Each reference is cumulative of art that was before the Patent Office during prosecution. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, No. IPR2017-01586, 2017 WL 6405100, at *6 (PTAB Dec. 15, 2017) (precedential) (relevant considerations include “the similarities and material differences between the asserted art and the prior art involved during examination” and “the cumulative nature of the asserted art and the prior art evaluated during examination”).

As an initial matter, the Petition’s conclusory allegation that the secondary references are not cumulative is insufficient to carry its burden. The Board has previously held that “Petitioner’s failure to conduct *any* analysis of whether its art was cumulative is, by itself, fatal under *AB* part one.” *Parse Biosciences, Inc. v. 10x Genomics, Inc.*, No. IPR2023-01033, 2023 WL 8789872, at *6 (PTAB Dec. 19, 2023) (emphasis in original); *see also Darfon Elecs. Corp. v. Shipman*, No. IPR2022-01008, 2022 WL 17408774, at *6 (PTAB Dec. 2, 2022) (denying institution where “Petitioner does not address whether the proffered art is cumulative to or substantially the same as the art considered during prosecution”); *Alarm.com*,

Inc. v. Vivint, Inc., No. IPR2022-00728, 2022 WL 16579639, at *8 (PTAB Nov. 1, 2022) (denying institution where “Petitioner does not address the similarities between [references] applied during prosecution of the challenged claims, and [the reference] relied upon in each of the asserted grounds”). The Petition here effectively has no cumulateness analysis. The Petition does not address any teachings that were before the Office. It simply asserts, without citation, that the references “are not like any references originally presented to the Office.” Petition at 32.

In any event, the secondary references are cumulative. The Petition relies on Paulekuhn and Bowker to teach the selection of sodium as a counterion and US '079 to teach use of single tablets for treating HIV-1 infections. *See id.* at 64, 66. These teachings were in front of the examiner, as Petitioner’s own grounds make clear. Petitioner’s Ground 1 does not incorporate any secondary references, meaning that *Petitioner* believes the secondary arts’ teachings are present in WO '323 and/or WO '351. This dooms Petitioner under *Advanced Bionics* Part 1. *See Parse Biosciences*, 2023 WL 8789872, at *6 (where Petitioner “relie[d] on Saleh and Song in the alternative for a similar teaching,” the Board determined that “Saleh is cumulative” of Song, which “was before the Examiner”); *Helena Labs. Corp. v. Sebia*, No. IPR2024-00801, 2024 WL 4557879, at *5 (PTAB Oct. 23, 2024) (art is cumulative where “Petitioner relies on both Shihabi and Huang as disclosing” the same teaching and Shihabi was presented during prosecution).

For example, in Ground 1, the Petition does not rely on any secondary references to motivate the selection of a sodium salt. Instead, the Petition states that “WO ’323 defines ‘pharmaceutically acceptable salt’ as including ‘salts derived from an appropriate base, such as an alkali metal (for example, sodium),’ which are typically prepared by reacting the metal hydroxide with a compound of this invention, examples being Li⁺, Na⁺, and K⁺ salts.” Petition at 57 (citing Ex. 1006, WO ’351). The Petition then contends that “DTG sodium was preferred over DTG free acid by WO ’351.” *Id.* That is, the Petition argues that WO ’351 alone would have led a skilled artisan to a sodium salt. In Grounds 2 and 3, the Petition uses Paulekuhn and Bowker for the same teachings, as a reason why “[a] POSA would have been especially drawn to sodium” salts. *Id.* at 65. Those teachings of Paulekuhn and Bowker are not materially different from the teachings of WO ’351 and WO ’323, which Petitioner concedes were “presented to the Office.” *Id.* at 32.

The sodium salt teachings of Paulekuhn and Bowker are also cumulative of the teachings of the Tivicay® and Triumeq® labels considered by the examiner. The Petition acknowledges that dolutegravir was “marketed as a sodium salt in Tivicay® and Triumeq® prior to the Effective Date,” relying on the Tivicay® and Triumeq® labels. *Id.* at 57 (citing Exs. 1022 and 1024). Both these labels were presented to the Patent Office and appear on the face of the ’802 patent. *See* Ex. 1002 at 789 (listing labels), 794 (examiner acknowledging she considered all citations not crossed out);

Ex. 2023 at 3 (“TIVICAY Product Label,” “TRIUMEQ Product Label”). Thus, Paulekuhn and Bowker are cumulative of the teachings of these labels too. *See, e.g., Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC*, No. PGR2023-00041, 2024 WL 249517, at *10 (PTAB Jan. 23, 2024) (finding art cumulative where it has “substantially the same teaching as in other prior art considered by the Examiner”); *Alarm.com*, 2022 WL 16579639, at *8 (“We find that the portions of Gregory that Petitioner relies upon as allegedly teaching a [limitation] as recited in claim 1, and corresponding limitations of claims 8 and 11, are duplicative of Kellen’s and Thomson’s teachings” that were before the examiner.).

Petitioner’s use of US ’079 in Ground 3 is similarly reflected in art of record. The Petition relies on US ’079 to teach “single tablets for treating HIV-1 infection.” Petition at 66. Petitioner’s Ground 1 analysis of the tablet limitation is again informative. In Ground 1, Petitioner cites several articles, including Shah and Sax, that it contends show a trend toward “provid[ing] single tablet ART regimens to HIV infected patients.” *See id.* at 37-38 (citing Ex. 1023, Shah et al., “Dolutegravir: A New Integrase Strand Transfer Inhibitor for the Treatment of HIV,” 34(5) *Pharmacotherapy* 506-20 (2014); Ex. 1025, Sax et al., “Tenofovir Alafenamide Vs. Tenofovir Disoproxil Fumarate in Single Tablet Regimens for Initial HIV-1 Therapy: A Randomized Phase 2 Study,” 67(1) *J. Acquired Immune Deficiency Syndromes* 52-58 (2014)). Both of those references are cited in an IDS and on the

face of the '802 patent. *See* Ex. 1002 at 789 (listing Shah and Sax), 794 (examiner acknowledging she considered all citations not crossed out); Ex. 2023 at 2-3.

The prosecution history further cements that the examiner was aware of single tablets for treating HIV-1 infection. For example, the examiner rejected claims in light of US 2007/0099902 to Dahl, which the examiner stated “teach[es] a bilayer tablet of efavirenz, emtricitabine, and tenofovir.” Ex. 1002 at 168.

Accordingly, the art Petitioner uses was either already before the Patent Office or substantially the same as art of record. *Advanced Bionics* Part 1 is satisfied for all of the Petition’s references.

B. *Advanced Bionics* Part 2: Petitioner Has Not Demonstrated That The Office Erred

The second part of the *Advanced Bionics* framework considers “whether the petitioner has demonstrated a material error by the Office.” *Advanced Bionics*, 2020 WL 740292, at *4. Petitioner’s burden is significant. Where, as here, “the alleged error is a disagreement with a specific finding of record by the Office, then ordinarily the petitioner’s required showing of material error must overcome persuasively that specific finding of record.” *Id.* And “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Id.* at *3.

Petitioner bears the burden of showing that the examiner materially erred. *Id.* Here too, the Petition fails to provide any thorough analysis of the examiner’s

alleged error. *See Siemens Mobility, Inc. v. Metrom Rail, LLC*, No. IPR2024-00947, 2024 WL 4827396, at *8 (PTAB Nov. 19, 2024) (finding no material error where “the Petition addresses the second *Advanced Bionics* factor with only five conclusory sentences.”).

Petitioner’s analysis of *Advanced Bionics* Part 2 focuses exclusively on WO ’323. Petition at 33. It has no argument or suggestion that the examiner erred in evaluating any other art or teachings. Petitioner suggests that “the examiner did not appreciate highly relevant disclosures from WO ’323.” *Id.* The examiner discussed WO ’323 in the notification of allowance, stating:

The next closest prior art of WO2014/100323 comprises administering the compound of Formula 1 at a different time than additional drugs such as tenofovir or emtricitabine. The prior art does not teach all three drugs within the same tablet. Applicants have shown a 30% higher exposure of bictegavir in a fixed dose combination of bictegavir, emtricitabine, and tenofovir alafenamide relative to its exposure when co-administered as a single agent of bictegavir with a fixed dose combination of emtricitabine and tenofovir alafenamide.

Ex. 1002 at 1051-1052.

Petitioner suggests that the examiner erred because, according to Petitioner, “WO ’323 is not limited to administration of Formula I (BIC) at a different time than additional drugs such as tenofovir or emtricitabine.” Petition at 33 (emphasis omitted). Petitioner cannot persuasively overcome the examiner’s specific findings of record regarding WO ’323. *See Advanced Bionics*, 2020 WL 740292, at *4.

The examiner correctly found that WO ’323 does not teach bictegravir, tenofovir, and emtricitabine all within the same tablet. Petitioner does not identify any specific example or statement that combined those three drugs. *See* Petition at 34. Instead, Petitioner relies only on a generic teaching that a pharmaceutical agent can be combined with other agents in various administrations. *Id.* (citing Ex. 1005 at 37:7-38:2, 38:13-21). The cited portions say “one embodiment” of the invention includes “pharmaceutical compositions comprising a compound disclosed herein, or a pharmaceutically acceptable salt thereof, in combination with one or more additional therapeutic agents.” Ex. 1005 at 37:13-15. That disclosure is entirely unspecific. There are innumerable compounds that fall within the “compound[s] disclosed” in WO ’323. *Id.* at 3:13-5:10 (defining broadest genus of compounds). And WO ’323 lists 15 classes of “additional therapeutic agents,” and most of those classes include numerous possible compounds. *Id.* at 38:1-39:22. Selecting the combination of bictegravir, tenofovir, and emtricitabine from that disclosure would be even harder than finding a needle in a haystack.

“It is well-settled that a narrow species can be non-obvious and patent eligible despite a patent on its genus.” *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1379 (Fed. Cir. 2014). For example, a species that was part of a broad genus disclosure would not be obvious. *See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1376 (Fed. Cir. 2006) (genus not invalidating where it did not “spell[] out a definite and limited class of compounds”). The genus disclosed in WO ’323 is enormous. Accordingly, the examiner did not err in finding that WO ’323 “does not teach all three drugs within the same tablet.” Ex. 1002 at 1051.

Similarly, “[a] species contained in a previously patented genus may be patentable if the species manifests unexpected properties or produces unexpected results.” *Abbvie*, 764 F.3d at 1380. The examiner explained that the claimed single tablet administration of bicitgravir, tenofovir, and emtricitabine does have unexpected properties. Ex. 1002 at 1051-1052. Specifically, the observed bicitgravir exposure was 30% higher compared to single agent bicitgravir with a separate tenofovir and emtricitabine tablet. As discussed above, that unexpectedly higher exposure was a previously unknown problem, and Gilead’s solution for a problem that a skilled artisan would not have recognized at the priority date would not have been obvious. *See, e.g., Novartis*, 611 F. App’x at 995; *Forest Labs.*, 257 F. Supp. 3d at 686. That the examiner correctly recognized the unexpected and surprising

properties of the claimed single tablet is another reason why the examiner did not err in considering WO '323. *See Padagis Israel Pharms. Ltd. v. Bausch Health Ireland Ltd.*, No. IPR2023-01114, 2024 WL 146121, at *8 (PTAB Jan. 12, 2024) (finding no material error in examiner's obviousness analysis where "the Examiner specifically credited Patent Owner's unexpected results showing").

Accordingly, Petitioner has not shown material error in the Office's prior consideration of WO '323. The circumstances of this case warrant denial under § 325(d).

VII. Conclusion

For the foregoing reasons, Gilead respectfully requests that the Board deny institution.

Dated: February 19, 2025

Respectfully submitted,

By: Meg E. Fasulo

Meg E. Fasulo (Reg. No. 75,820)

J. Scott McBride (*pro hac vice* requested)

Rebecca T. Horwitz (*pro hac vice*
requested)

BARTLIT BECK LLP

54 West Hubbard Street, Suite 300

Chicago, IL 60654

(312) 494-4400

Taylor Kelson (*pro hac vice* requested)

BARTLIT BECK LLP

1801 Wewatta Street, Suite 1200

Denver, CO 80202

(303) 592-3100

Counsel for Patent Owner

CERTIFICATE OF WORD COUNT

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the Microsoft Office word count for the foregoing Patent Owner's Preliminary Response Under 35 U.S.C. § 313 and 37 C.F.R. § 42.107, excluding the table of contents, table of authorities, list of exhibits, certificate of word count, and certificate of service, totals 11,244 words, which is less than the 14,000 words allowed under 37 C.F.R. § 42.24(b)(1).

By: Meg E. Fasulo
Meg E. Fasulo (Reg. No. 75,820)
BARTLIT BECK LLP
54 West Hubbard Street, Suite 300
Chicago, IL 60654
Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned certifies, that on this 19th day of February, 2025, the foregoing document is being served by e-mail on counsel of record for Petitioner as follows:

alarsen@merchantgould.com
csorenson@merchantgould.com
CiplaBictegravirIPR@merchantgould.com

By: Meg E. Fasulo
Meg E. Fasulo (Reg. No. 75,820)
BARTLIT BECK LLP
54 West Hubbard Street, Suite 300
Chicago, IL 60654

Counsel for Patent Owner