

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 22-615 (MN)
	)	(CONSOLIDATED)
LUPIN LTD., LAURUS LABS LIMITED,	)	
and CIPLA LIMITED,	)	
	)	
Defendants.	)	

JOINT CLAIM CONSTRUCTION BRIEF

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I. AGREED-UPON CONSTRUCTIONS

The parties have agreed to the following constructions:

Claim	Term	Construction
'342 patent: claims 12, 11; '067 patent: claims 1, 10	“therapeutically effective amount”	“An amount of the claimed compound, which when administered to a patient in need thereof, is sufficient to effect treatment for disease-states, conditions, or disorders for which the compounds have utility.”

II. DISPUTED CONSTRUCTIONS

**A. “about [5.5°, 16.1°, 23.3°] 2-θ ±0.2° 2-θ”
(’342 patent: claim 3; ’067 patent: claims 1, 10)**

Gilead’s Proposed Construction	Defendants’ Proposed Construction
“within 0.2° 2-θ above or below the recited peak, as rounded to the nearest tenth of a degree (0.1°) 2-θ.”	“within 0.2° 2-θ above or below [5.5°, 16.1°, 23.3°].” -or- Indefinite.

1. Plaintiff’s Opening Position

Certain claims of the ’342 and ’067 patents are directed to the positions of specific peaks in the diffraction pattern of bictegravir sodium as measured by X-ray powder diffraction (XRPD). As relevant to the parties’ dispute here, claim 3 of the ’342 patent and claims 1 and 10 of the ’067 patent are directed to a compound “characterized by an X-ray powder diffraction (XRPD) pattern having peaks at about 5.5°, 16.1°, and 23.3° 2-θ ±0.2° 2-θ.”

The parties’ dispute amounts to a dispute about precision—how to understand the claims’ recitation of peak positions that are “about” a numerical value expressed to the tenths of a degree 2θ. The claims at issue require a comparison between the recited XRPD peak positions and the XRPD peak positions of an accused compound, as measured by experiment. When doing that

comparison, the question at the core of the parties' dispute is whether an experimental XRPD peak position should first be rounded to the same degree of precision as the peak positions recited in the claims before the comparison is performed. Plaintiff says yes; Defendants say no.

The Plaintiff's claim construction is supported by the intrinsic evidence, namely the claim's use of the term "about" to reference the particular claimed peak positions and the patent's consistent reporting of peak positions rounded to the precision of tenths of a degree (one digit past the decimal). A person of skill would understand the claim's description of peak positions in this manner to require rounding experimental peak positions (which often include more digits past the decimal) to tenths of a degree in order to make a meaningful comparison within the range of variability ($\pm 0.2^\circ$ 2- θ).

a. Plaintiff's Proposed Construction Is Supported by the Intrinsic Evidence

As an initial matter, the claim language itself supports Plaintiff's construction in that it recognizes the limitations on precision in its reported values with its use of the word "about" to express each value and its associated margin of error. To describe a value as "about 5.5°" is to make clear that it is not exactly or precisely that numerical value. A POSA would recognize that "about" incorporates a degree of variability and, with respect to reported XRPD peak positions, would include rounding to the reported degree of precision.

Plaintiff's construction is also supported by the specification's disclosure of reported peak positions. The disclosure of the patents confirms that experimental XRPD peak positions should be rounded to the nearest tenth of a degree before comparison to the claimed peak positions. All of the XRPD peak positions provided in the patents are reported with values to the tenth of a degree

20.¹ For example, Table 1 of the '342 and '067 patents reports the XRPD peak positions of bictegravir sodium Form I rounded to the nearest tenth of a degree (even though the peak positions from the underlying experiments would have been identified by the instrument's software to the thousandth or ten-thousandth of a degree):

TABLE 1	
XRPD peaks for crystalline forms of Formula II Form I	
Formula II Form I	
Peak Position [°2 θ]	Relative Intensity [%]
5.5	100.0
16.1	87.3
17.9	22.4
19.5	38.0
22.1	61.8
22.5	42.2
23.3	60.4
26.6	27.3
28.5	42.9

Ex. 1, '342 patent at 24:5–20; Ex. 2, Chyall Decl. at ¶ 41. Similarly, the details of the embodiments reported in the specification are all listed with XRPD peak position values rounded to the nearest tenth of a degree 2 θ . See Ex. 1, '342 patent at 9:32–60, 23:49–56. And the XRPD peak positions described in the claims of '342 (claims 3–6) and '067 patents (claims 1–4 and 10) are rounded to the nearest tenth of a degree 2 θ .

¹ Fundamental to this is the POSA's understanding that 0.3 is not the same as 0.30 or 0.300—digits, called significant digits, matter. The number of reported digits is necessarily reflective of the precision of the value at issue. See Ex. 2, Chyall Decl. at ¶¶ 43–46.

b. Plaintiff's Proposed Construction Is Consistent With the Inherent Uncertainty in XRPD Measurements

The rounding that is part of Plaintiff's construction is also correct because experimental peak positions in XRPD diffraction patterns are necessarily subject to uncertainty. XRPD is an analytical technique that can be used to distinguish between different crystalline solid forms (i.e. polymorphic forms) of the same chemical compound. Ex. 2, Chyall Decl. at ¶ 33. Figures 1 and 8 of the '342 and '067 patents depict XRPD diffractograms. *See* Ex. 1, '342 patent at Figs. 1, 8. The XRPD pattern obtained for a specific polymorph of a compound, expressed by identifying the positions (measured in degrees 2θ) of specific peaks within that pattern, are unique to that polymorph and "provide distinctive information about the polymorph's three-dimensional structure." Ex. 2, Chyall Decl. at ¶ 34. Often these diffraction patterns and corresponding peaks are referred to as the polymorph's fingerprint.

But XRPD analysis is not an exact process, and variability and uncertainty in the results exists. As the patents explain, "[t]hose skilled in the art recognize that the measurements of the XRPD peak locations and/or intensity for a given crystalline form of the same compound will vary within a margin of error. The values of degree 2θ allow appropriate error margins. Typically, the error margins are represented by $\pm$." Ex. 1, '342 patent at 23:49–52. The patents further identify certain sources of this uncertainty: "the sample preparation techniques, the calibration techniques applied to the instruments, human operational variation, and etc." *Id.* at 23:56–58.

However, despite the inherent uncertainty in peak measurements, laboratory XRPD instruments and software (such as the X'Pert Highscore version 2.2c software that was used to analyze the XRPD data described in the '342 and '067 patents) report out peak positions from a given sample to a very high degree of precision, typically the thousandth or ten-thousandth of a degree. Ex. 2, Chyall Decl. at ¶ 39. A POSA would appreciate that, when comparing different

experimental XRPD diffractograms of the same polymorph, comparing the positions of XRPD peaks at that level of precision is not meaningful because of the uncertainty that is inherent in experimentally determined XRPD peak positions. Ex. 2, Chyall Decl. at ¶¶ 38–39.

A POSA would thus understand the need to round the value of an experimentally determined XRPD peak position to an appropriate degree of precision before comparing it with peak positions from other experiments, or reference peak positions such as the claimed peak positions. For the '342 and '067 patents, a POSA would appreciate that the appropriate rounding would be to the nearest tenth of a degree. Ex. 2, Chyall Decl. at ¶¶ 39–41.

Therefore, for any infringement analysis, claim 3 of the '342 patent and claims 1 and 10 of the '067 patent require a comparison of the experimental XRPD peak positions of potentially infringing material to the claimed XRPD peak positions of “about 5.5° , 16.1° , and 23.3° $2-\theta \pm 0.2^\circ$ $2-\theta$.” And ultimately, the parties’ claim construction dispute is about how this comparison is performed. The disclosure of the patents as well as Dr. Chyall’s explanation of what a POSA would understand about XRPD analysis both confirm that Plaintiff’s proposed construction captures the correct procedure for comparison: First, round the experimental value to the nearest tenth of a degree, which is the appropriate precision for comparison to the claim. Second, determine whether the experimental peak position (as appropriately rounded to reflect the precision of the claim) is within the claimed range of, for example, 5.5° $2\theta \pm 0.2^\circ$ 2θ (i.e. 5.3° to 5.7° 2θ). The result is that “experimental peak positions of 5.2863° 2θ (which is rounded to 5.3°), 5.5442° 2θ (which is rounded to 5.5°), or 5.7334° 2θ (which is rounded to 5.7°) are all ‘about $[5.5^\circ]$ $2-\theta \pm 0.2^\circ$ $2-\theta$.’” Ex. 2, Chyall Decl. at ¶ 44. Conversely, “experimental peak positions of 5.2429° 2θ (which is rounded to 5.2°) or 5.7521° 2θ (which is rounded to 5.8°) are not ‘about $[5.5^\circ]$ $2-\theta \pm 0.2^\circ$ $2-\theta$.’” *Id.* This is

the correct result according to both the disclosure of the patents and the understanding of a POSA, and it is appropriately captured by Plaintiff's proposed construction.

c. Defendants' Proposed Construction Renders "About" Superfluous

Defendants propose that this claim term means "within 0.2° $2\text{-}\theta$ above or below [5.5° , 16.1° , 23.3°]." If Defendants' construction were applied such that the value of the experimental peak position was first rounded to the appropriate precision (*i.e.* to the nearest tenth of a degree 2θ), then Defendants' construction would be equivalent to Plaintiff's construction. But this is not Defendants' proposal—instead, Defendants propose that no rounding should occur.

Defendants' position is contrary to the claim language. As discussed above, the rounding step that is encompassed by Plaintiff's proposed construction gives meaning to the word "about." The presence of the modifier "about" in the claim language linguistically confirms that there must be some amount of permissible variation in the claimed XRPD peak positions. In context, this indicates that the peak positions should be rounded to the nearest tenth of a degree. *See* Ex. 2, Chyall Decl. at ¶ 43. Defendants' proposed construction would render the word "about" superfluous. Defendants' proposed construction is presumptively incorrect for this reason. A "claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). "[I]nterpretations that render some portion of the claim language superfluous are disfavored." *Power Mosfet Techs., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1410 (Fed. Cir. 2004).

d. Defendants' Proposed Construction Treats the Recited Peak Positions and Uncertainty as Infinitely Precise

In fact, Defendants' construction goes even further than reading "about" out of the claim language—Defendants' construction proposes the opposite. Defendants' proposal that no rounding whatsoever should occur treats the claimed peak positions (5.5° , 16.1° , and 23.3° 2θ), as well as

the associated uncertainty of $\pm 0.2^\circ 2\theta$, as exact or infinitely precise values. For defendants, “ $5.5^\circ 2-\theta \pm 0.2^\circ 2-\theta$ ” means “ $5.5000\dots^\circ 2-\theta \pm 0.2000\dots^\circ$ ” (i.e. $5.3000\dots^\circ$ to $5.7000\dots^\circ 2\theta$). For example, under Defendants’ proposed construction, an experimental peak position of $5.2999^\circ 2\theta$ is not between 5.3° to $5.7^\circ 2\theta$, and is thus not “about $5.5^\circ 2-\theta \pm 0.2^\circ 2-\theta$,” even though 5.2999° rounds to 5.3° when that peak position is evaluated with the same degree of precision as the peak positions in the claim. As Dr. Chyall explains, Defendants’ proposed construction considers “ 5.5° ,” “ 16.1° ,” and “ 23.3° ” to equal $5.5000\dots^\circ$, $16.1000\dots^\circ$, and $23.3000\dots^\circ$, and “ 0.2° ” as equal to $0.2000\dots^\circ$. Ex. 2, Chyall Decl. at ¶ 46.

And as a POSA would appreciate, precision (and digits beyond the decimal) matters—“ 0.2° ” does not have the same meaning as “ $0.2000\dots^\circ$,” and “ 5.5° ” does not have the same meaning as “ $5.5000\dots^\circ$.” A POSA intending to indicate that recited peak positions were precise to the full reporting limit of known XRPD instruments and software would indicate that expressly, by saying “ 5.5000° .” They would not say “about 5.5° .” Ex. 2, Chyall Decl. at ¶¶ 48–49.

Further, as Dr. Chyall explains, the entire concept of exactly precise peak positions is inconsistent with what a POSA would understand about the nature of XRPD characterization. Experimental measurements of XRPD peak positions are inherently subject to a degree of uncertainty from a variety of factors including different sample preparation, different experimental conditions, different laboratories, different instruments, etc. Ex. 2, Chyall Decl. at ¶ 48. Dr. Chyall explains that even the concept of “exact values” for experimentally determined XRPD peak positions doesn’t make sense, because the notion that the position of a peak could be known exactly from an XRPD experiment is inconsistent with what a POSA would understand about XRPD analysis. Ex. 2, Chyall Decl. at ¶ 49.

Peak positions from different experiments must be rounded to the appropriate precision before they can be meaningfully compared. Both the disclosure of the '342 and '067 patents and the independent understanding of a POSA confirm that the appropriate procedure with respect to these claims is to round experimental values to the nearest tenth of a degree, matching the degree of precision expressed in the claims themselves, and then perform the comparison to the claimed peak position subject to the claimed range of uncertainty.

e. Defendants Have Not Disclosed an Indefiniteness Argument

Defendants' proposed construction of this claim term, as reflected in the parties' Amended Joint Claim Construction Chart, indicates Defendants' position that Defendants' proposed construction should be adopted or the term is indefinite. *See* D.I. 252. But Defendants' Amended Final Invalidity Contentions do not advance any theory of invalidity that is premised on the alleged indefiniteness of this claim term—in fact, Defendants' Amended Final Invalidity Contentions make no allegation that claim 3 of the '342 patent or claims 1 and 10 of the '067 patent are indefinite. *See* Defendants' Amended Final Invalidity Contentions at 272–276, 319–321. Defendants have therefore waived any argument that claim 3 of the '342 patent or claims 1 and 10 of the '067 patent are indefinite, including because this claim term is indefinite. To the extent that Defendants are later granted leave to assert that these claims are indefinite, Plaintiff reserves all rights to respond.

2. Defendants' Answering Position

Defendants agree that the dispute over this claim term centers upon the level of precision required by the relevant claims for the location of an X-ray powder diffraction peak of a powder diffraction pattern as measured by “degrees 2-theta,” or “ $2-\Theta$.” The common specification for the '342 and '067 Patents is explicit: the claimed peak positions are afforded a margin of error of 0.2° $2-\Theta$ above and below each peak recited in the relevant claims, and this is the normal margin

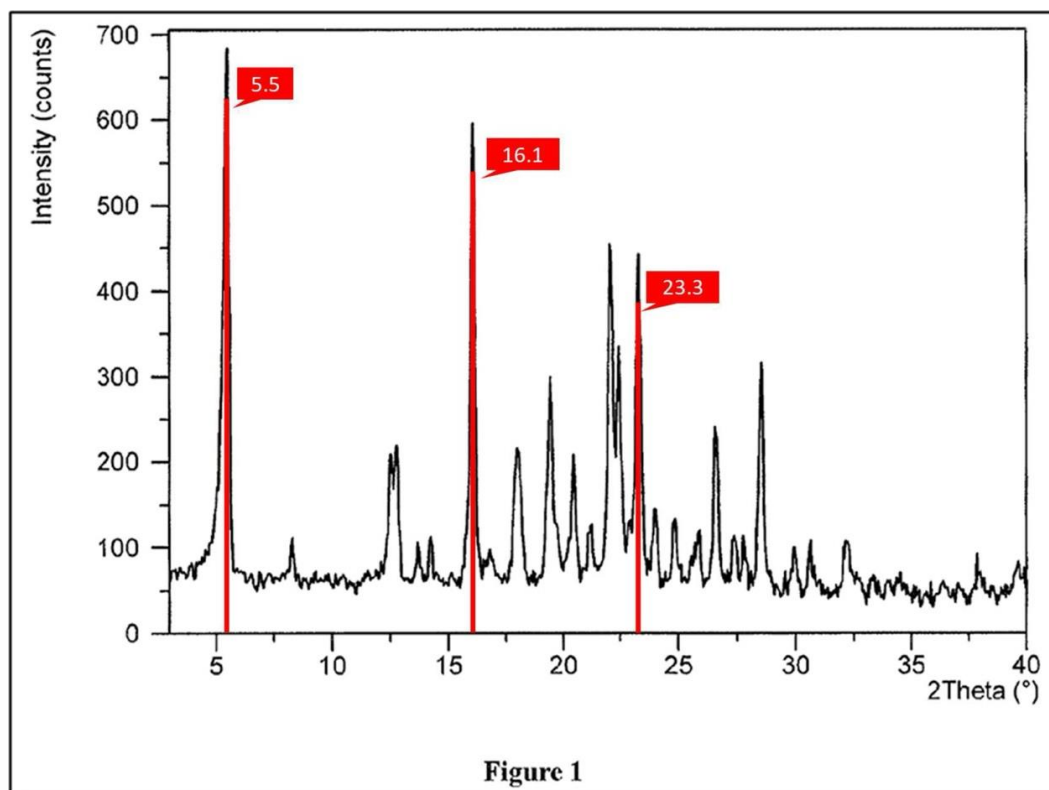
of error afforded to XRPD peaks. “About” references this normal margin of error afforded to the measurements that it modifies. As such, “about” in the claim language is meant simply to include (and describe) the recited range around the claimed peak positions. *See* Ex. 1 (’342 Patent), 6:34–37 (“Reference to ‘about’ a value or parameter herein includes (and describes) embodiments that are directed to that value or parameter per se. For example, description referring to ‘about X’ includes description of ‘X’.”).

Gilead proposes a construction that is not consistent with the specification, in an effort to revise the margin of error it claimed before the Patent Office. Gilead does this by extrinsic evidence alone, as the intrinsic evidence does not mention rounding. There is, however, an explicit instruction in the specification on how to apply the recited margin of error to determine peak location, which should control. Ex. 1 (’342 Patent), 23:49–62. In sum, the inventors chose to define the margin of error, and “about” explicitly in the specification, which should control. The extrinsic evidence before the Court does not justify a revision to the clear lexicography provided in the specification.

a. The Claims Account for the Inherent Uncertainty in XRPD Measurements by Reciting a Specific Margin of Error

Claim 3 of the ’342 Patent, and claims 1 and 10 of the ’067 Patent, share a common phrase defining a sodium salt of Formula II (“bictegravir sodium”) characterized as being crystalline, and further “. . . characterized by an x-ray powder diffraction (XRPD) pattern having peaks at about 5.5°, 16.1°, and 23.3° 2- θ $\pm$ 0.2° 2- θ .” *See* Ex. 1 (’342 Patent), 33:19–36 (claims 1-3); Ex. 3 (’067 Patent), 33:8–26; 34:1–21 (claims 1 and 10). The claims recite peak positions to the tenth of a degree, with an explicitly recited margin of error of $\pm$ 0.2° 2- θ .

An XRPD pattern is defined by the common specification² to be “represented by a diagram plotting the intensity of the peaks versus the location of the peaks, i.e., diffraction angle $[2-\Theta]$ (two theta) in degrees.” See Ex. 1 (’342 Patent), 23:40–42. The peak locations are plotted on the horizontal, or x-axis of the diagram (also called a diffractogram), and the intensity of those peaks are on the vertical or y-axis, as seen in Figure 1:



Ex. 1 (’342 Patent), Fig. 1 (annotated in red to emphasize the claim 3 peak locations at 5.5, 16.1 and 23.3° 2- θ). The specification reports that “the XRPD peaks for the crystalline forms of [bictgravir sodium] of the present invention can be found below in Table 1.” *Id.* at 23:65–24:20. Table 1 is reproduced below:

² The ’342 and ’067 Patents share a common specification; citations are either to the ’342 Patent or ’067 Patent alone for brevity.

TABLE 1		
XRPD peaks for crystalline forms of Formula II Form I		
	Peak Position [°2θ]	Relative Intensity [%]
	5.5	100.0
	16.1	87.3
	17.9	22.4
	19.5	38.0
	22.1	61.8
	22.5	42.2
	23.3	60.4
	26.6	27.3
	28.5	42.9

As can be seen, the peak positions are reported in units of tenths of a degree 2-θ, and nothing further. The specification provides no XRPD peak positions in anything other than tenths of a degree, and there is no mention of rounding. However, as the specification explains, “[t]hose skilled in the art recognize that the measurement of the XRPD peak locations and/or intensity for a given crystalline form of the same compound will vary within a margin of error.” Ex. 1 (’342 Patent), 23:49–52. In addition, the specification explains that “[t]he values of degree [2-θ] allow [for] appropriate error margins.” *Id.* at 23:52–53. It explains further that the error margins are represented by the “plus/minus” symbol (±). *Id.* at 23:53–54. Importantly, the specification also recognizes that “those skilled in the art recognize that the appropriate error of margins for a XRPD can be ±0.5; ±0.4; ±0.3; ±0.2; ±0.1; ±0.05 or less.” *Id.* at 23:60. Among these ranges, the Patentee chose to claim an error margin of ± 0.2.

Later in the specification (at column 27) the patentee also identifies the software used to generate peak locations to be the “X’Pert Highscore version 2.2c” software program, with “X’Pert data viewer version 1.2d.” Ex. 1 (’342 Patent), 27:15–19. That software was used to report peak positions and relative intensities of the peaks of Table 1, and produced the diffractogram that is Figure 1. *Id.* at 27:21–39. No XRPD data reported in the common specification recites any peak

position with a precision to the thousandth or ten-thousandth of a degree, or even a hundredth of a degree. The disclosed peaks have a precision of a tenth of a degree, and no further information about them is provided.

b. Defendants’ Proposal Comports With How the Specification Clearly and Unambiguously Defines “About”

As noted above, the specification also states that “[r]eference to ‘about’ a value or parameter herein includes (and describes) embodiments that are directed to that value or parameter per se.” Ex. 1 (’342 Patent), 6:33–35. It also provides an example, stating that a “description referring to ‘about X’ includes [a] description of ‘X’.” *Id.* at 6:35–36. There is no mention in the specification of any intent to employ “about” as referencing anything other than the margin of error described in the relevant claims, *i.e.*, 0.2° $2\text{-}\theta$.” In short, the specification itself advises that the term “about” is intended to direct the person of ordinary skill to embodiments containing a value or parameter, *e.g.*, the peak values at 5.5, 16.3, and 23.3. This allows for the recited value to fall within a broader range, *e.g.*, a range of error inherent to the instrument measuring that value. This definition does not suggest rounding, and certainly no rounding of values with any level of specificity greater than tenths of a degree. The specification confirms that “XRPD peak locations for a given crystalline form of the same compound will vary within a margin of error” and discloses several options for the “appropriate error of margins” to use: “ ± 0.5 ; ± 0.4 ; ± 0.3 ; ± 0.2 ; ± 0.1 ; and ± 0.05 ; or less.” *Id.* at 23:54–60. In the claims, the range allowed by the term “about” is defined by the recited margin of error of $\pm 0.2^{\circ}$ $2\text{-}\theta$ for each peak value.

Gilead’s construction asks the Court to rewrite “about” as described in the specification to mean something else entirely—“rounding to the nearest tenth of a degree (0.1°) $2\text{-}\theta$.” This argument is only supported with extrinsic evidence and is directly at odds with the inventors’ own description of the term. Nothing in the specification regarding “about” relates to a rounding step.

The use of “about” in the specification better comports with inherent errors in XRPD peak positions, and the provision of a range of error surrounding a peak value *per se*, e.g., the specific values 5.5, 16.1, and 23.3, recited in the claims.

Defendants’ proposed construction is consistent with the common specification. Defendants propose that “about” refers to the margin of error assigned to each XRPD peak with the claim language $\pm 0.2^\circ$ 2- θ , and nothing more. This is a common, and well accepted, margin of error assigned to XRPD peak values, given the variability inherent in such an analytical technique. *See* Ex. 2, Chyall Decl. at ¶ 38 (citing U.S. Pharmacopeia 35, Chapter 941, X-Ray Diffraction (rev. 2011)). The common specification elected to report the peak positions to a tenth of a degree 2- θ . The claims were drafted by the applicant with the same level of precision (to the tenth of a degree 2- θ) with the assigned margin of error to account for the inherent imprecision in measurement of those peaks.

Defendants’ construction employs the same methodology given by the specification to calculate the range afforded by the claims for a given peak. This range of $\pm 0.2^\circ$ 2- θ accounts for the imprecision of measurement when it comes to defining the location of a peak on the x-axis of an XRPD pattern. As an example, the recited value of “about 5.5” allows some variability around that peak *per se* so long as that variability is within the claimed error of $\pm 0.2^\circ$ 2- θ . It defines a range that includes (and describes) the claimed peak values, consistent with the meaning of “about” in the specification.

If that were not the case, then “about [5.5°, 16.1°, 23.3°] 2- θ $\pm 0.2^\circ$ 2- θ ” would allow for expansion of the $5.5^\circ \pm 0.2^\circ$ 2- θ , $16.1^\circ \pm 0.2^\circ$ 2- θ , and $23.3^\circ \pm 0.2^\circ$ 2- θ range into something entirely unknown.

c. Gilead's Proposed Construction Is Not Supported by the Intrinsic Record

Consistent with the claim language and specification, the recited peak ranges are $5.5^{\circ} \pm 0.2^{\circ}$ 2- θ , $16.1^{\circ} \pm 0.2^{\circ}$ 2- θ and $23.3^{\circ} \pm 0.2^{\circ}$ 2- θ . Nothing in the intrinsic evidence supports Gilead's construction of "about". Gilead relies principally upon an extrinsic expert declaration in its effort to revise the definition of "about," which should be the margin of error it chose when writing its patent claims. The data in Table 1 reports only a precision to the "tenth of a degree" for each peak, and the claims assign a margin of error of $\pm 0.2^{\circ}$ 2- θ . The term "about" is also explicitly defined, and it does not mention any rounding step. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. See *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996)). Gilead's proposed construction is simply not supported by the intrinsic record and should therefore be rejected.

d. Defendants Have Maintained Their Contingent Indefiniteness Argument Since September 6, 2023

Gilead is mistaken in its summary of the record with regard to Defendants' position on indefiniteness concerning the "about" claim term. Defendants first disclosed this specific indefiniteness position on September 6, 2023, with their Initial Identification of Proposed Claim Terms and Constructions. See Ex. 4 (Defendants' Initial Identification of Proposed Claim Terms and Constructions). The Federal Circuit has recognized that indefiniteness is "inextricably intertwined with claim construction." *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1379 (Fed. Cir. 1999). Defendants' position is that if "about" means something other than what the specification defines it to mean, then the claims to XRPD values employing that term are indefinite, because the intrinsic record does not inform "those skilled in the art about the scope of

the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments Inc.*, 572 U.S. 898, 910 (2014).

3. Plaintiff’s Reply Position

The two claim terms, “about” and “ $\pm 0.2^\circ$ 2- θ ,” have different roles in the claim language. The term “ $\pm 0.2^\circ$ 2- θ ” indicates the claimed *range* of 2- θ values above and below a specific peak position. The claim language is clear that the range of 2- θ values claimed are 0.2° above and below a peak position (for example, 5.3° – 5.7° with respect to 5.5°). “About” indicates that this claimed range for the peak positions contains *imprecision* at the boundaries of the range. The patent’s specification and scientific practice demonstrate that the level of imprecision allowed by “about” requires rounding experimental 2- θ values to the nearest tenth of a degree.

Defendants’ proposed construction arbitrarily conflates the terms “about” and “ $\pm 0.2^\circ$ 2- θ ” as both indicating the margin of error of the specific peak position, rendering the term “about” meaningless. Their construction is at odds with principles of claim construction, the patent’s specification, and scientific practice. Moreover, Defendants never answer the necessary question of how to compare more-precise experimental XRPD values, such as those measured to the hundredth or thousandth of a degree, to the claim. Gilead’s construction not only answers that practical question with scientific precision, but also gives meaning to each claim term without creating surplus language, is supported by the patent’s specification, and is consistent with scientific practice.

a. Only Gilead’s Construction Gives Meaning to Each Claim Term and Is Supported by the Intrinsic and Extrinsic Evidence

Claim constructions should not render any claim language superfluous, meaningless, or redundant. But that is exactly what Defendants have done—they expressly negate any separate meaning for the word “about.” Gilead’s construction, however, recognizes and accounts for the

separate meanings for these two phrases: “about” recognizes the imprecision in measuring XRPD peak positions and allows rounding of experimental values to the nearest tenth of a degree; “ $\pm 0.2^\circ$ 2- θ ” is the margin of error for the claimed peak. Where two different words or phrases are used in the same claim, it suggests that the words have different meanings. *Apple Inc. v. Firstface Co.*, Nos. 2021-1001 & -1002, 2021 WL 4156323, at *2 (Fed. Cir. Sept. 13, 2021).

The specification, including the portions Defendants cite, supports Gilead’s construction, not Defendants’. Defendants twice quote the specification’s disclosure that “those skilled in the art recognize that the appropriate error of margins for a XRPD can be ± 0.5 ; ± 0.4 ; ± 0.3 ; ± 0.2 ; ± 0.1 ; ± 0.05 or less.” *Supra* at 11 (quoting Ex. 1, ’342 patent at 23:60). The fact that the patentee recited one of these margins of error (± 0.2) in the claims means nothing more than describing the claimed ranges of 2- θ values. It does not support the Defendants’ contention that “about” means “ $\pm 0.2^\circ$ 2- θ .” Critically, Defendants ignore³ the immediately preceding disclosure in that paragraph:

Those skilled in the art recognize that the measurements of the XRPD peak locations and/or intensity for a given crystalline form of the same compound will vary within a margin of error. The values of degree 2 θ allow appropriate error margins. Typically, the error margins are represented by “ $\pm$ ”. For example, the degree 2 θ of about “8.7 ± 0.3 ” denotes a range from about 8.7+0.3, i.e., about 9.0, to about 8.7-0.3, i.e., about 8.4.

’067 patent at 23:49–56 (emphasis added). As this disclosure makes clear it is the “ $\pm$,” not “about,” that represents the quantity that is the margin of error. It also makes clear that “about,” in contrast, denotes the uncertainty at the *boundaries* of the claimed range. For example, the specification explains that “about 8.7 ± 0.3 ” denotes a range from “about 9.0” to “about 8.4.” The “about”

³ Elsewhere, Defendants cite (though do not quote) this disclosure and state that it is “an explicit instruction in the specification on how to apply the recited margin of error to determine peak location, which should control.” *Supra* at 9. Gilead agrees that this disclosure should control, and it confirms that Gilead’s proposed construction is correct.

modifies the endpoints of the margin of error, inclusive of the entire range of 2- θ values, not simply the specific peak position of 8.7.

And contrary to Defendants' suggestion, the disclosure that a "description referring to 'about X' includes [a] description of 'X'" is in harmony with the portion of the specification just discussed and also supports Gilead's proposed construction. *Supra* at 9; '067 patent at 6:35–36. The disclosure that "'about X' includes [a] description of 'X'" indicates that "about X" includes values other than exactly X, further confirming that "about" encompasses uncertainty.

Finally, Gilead's position is confirmed by extrinsic evidence regarding the meaning of the claim to a POSA, to which Defendants have no substantive response. Gilead submitted with its opening brief the declaration of Leonard Chyall, Ph.D., an expert in the synthesis and analytical testing of pharmaceutical solids, including XRPD. Ex. 2, Chyall Decl. at ¶ 4. Defendants argue that this means Gilead supports its proposed construction "by extrinsic evidence alone." *Supra* at 9. This is an incorrect characterization of both Gilead's opening brief and Dr. Chyall's declaration. Dr. Chyall's declaration *itself* is extrinsic evidence, but the substance of his declaration is largely an explanation of how and why a POSA would understand the *intrinsic* evidence to support Gilead's proposed construction and to be inconsistent with Defendants. *See generally* Ex. 2, Chyall Decl. at ¶¶ 38–49. "The inquiry into how a person of ordinary skill in the art understands a claim term" is the question at the core of any claim construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*), *cert. denied*, 546 U.S. 1170 (2006).

b. Defendants Ignore the Central Question of How to Compare Experimental Data to the Claimed Ranges of Peak Positions

Defendants ignore the central question of how to compare experimental data to the claimed ranges of peak positions. Gilead's opening brief explained that XRPD instruments and their associated software typically generate experimental peak positions expressed to the thousandth or

ten-thousandth of a degree. Defendants do not, and cannot, dispute that characterization. The practical question is how to compare such experimentally determined XRPD peaks to the claims. For example, how should one determine whether an experimental value of $5.2784^\circ 2-\theta$ or $5.2999^\circ 2-\theta$ is “about $5.5^\circ 2-\theta \pm 0.2^\circ 2-\theta$ ”? Gilead provided a detailed answer, explaining that the proper procedure is to first round $5.2784^\circ 2-\theta$ or $5.2999^\circ 2-\theta$ to the nearest tenth of a degree (i.e., $5.3^\circ 2-\theta$), and then compare that value to the claimed range of “about $5.5^\circ 2-\theta \pm 0.2^\circ 2-\theta$,” i.e. about $5.3^\circ 2-\theta$ to about $5.7^\circ 2-\theta$. *See supra* at 5–6. Defendants do not provide an alternative answer—they ignore the question altogether.

Defendants note that all peak positions reported in the patents “have a precision of a tenth of a degree [2- θ],” *supra* at 12, but do not dispute that the patent software would have reported the peak positions to a much higher degree of precision. For example, Defendants reference the undisputed fact that the patent’s reported peak positions were generated by the “X’Pert Highscore version 2.2c” software program, with “X’Pert data viewer version 1.2d.” *Supra* at 11. Defendants thus tacitly acknowledge that the inventors *rounded* the experimental data to the tenth of a degree, just as Gilead’s construction proposes.

Rather than address the key question of how to compare an experimental peak value to the claimed range, Defendants instead repeatedly focus on the absence of the word “rounding” in the specification *Id.* at 2, 4–7. By suggesting that no rounding should occur, Defendants indicate that “about $5.3^\circ 2-\theta$ ” (i.e. the lower bound of “about $5.5^\circ 2-\theta \pm 0.2^\circ 2-\theta$ ”) should be treated to mean *exactly* $5.3000\dots^\circ 2-\theta$ rather than *about* $5.3^\circ 2-\theta$. Defendants’ construction would thus lead to the conclusion that an experimental value of $5.2999^\circ 2-\theta$ does not fall within the claims. But such a result defies scientific practice and common sense, and it negates the claim term “about.” It is undisputed that XRPD instruments and software generate experimental peak positions with much

higher precision than to the tenth of a degree, which must be compared to the claims. The claim term “about” facilitates that comparison.

c. The Patentee Was Not Engaged in Lexicography

Defendants argue that the specification amounts to “clear lexicography” regarding the meaning of the word “about.” *Supra* at 9. The standard to find lexicography is high— “[w]hen a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description.” *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005). No such clear intent is present, because nothing in the specification suggests an intention to redefine the term “about.” Defendants never explain where the patentee supposedly redefined that term or what that definition is. Defendants appear to suggest that the patentee redefined that word “about” to mean “exactly.” *See, e.g., Supra* at 11 (arguing that “the Patentee chose to claim an error margin of $\pm 0.2[^\circ 2-\theta]$ ”). But there is no mention in the specification that the recited peak positions and error ranges be so infinitely precise—the specification never once suggests, never mind says, that “about $5.5^\circ 2-\theta \pm 0.2^\circ$ ” means “exactly $5.3000\dots^\circ - 5.7000\dots^\circ 2-\theta$.” The specification’s discussion of the term “about” provides insight and confirmation regarding its plain and ordinary meaning, which is reflected in Gilead’s proposed construction and is in opposition to Defendants’ overly precise construction.

d. Defendants’ Indefiniteness Argument Is Both Waived and Meritless

Defendants’ indefiniteness argument is waived. In their Initial Identification of Proposed Claim Terms and Constructions, served September 6, 2023, Defendants alleged that this claim term was indefinite if Defendants’ proposed construction was not adopted. *Supra* at 14. But in their Amended Final Invalidity Contentions, served on July 26, 2024, Defendants never allege that

claim 3 of the '342 patent or claims 1 and 10 of the '067 patent are indefinite, *see* Defendants' Amended Final Invalidity Contentions at 272–276, 319–321, despite making arguments that other claim terms are indefinite, *see id.* at 272–276, 319–321, 492–493. A party “waive[s] its right to present at trial an invalidity theory not disclosed in its final contentions.” *Pharmacyclics LLC v. Cipla Ltd.*, Nos. 18-192 & 19-434, 2020 WL 6581643, at *2 (D. Del. Nov. 10, 2020).

In any event, Defendants' indefiniteness argument is without merit. Defendants are incorrect that Gilead's proposed construction “would allow for expansion of the $5.5^{\circ} \pm 0.2^{\circ} 2-\theta$, $16.1^{\circ} \pm 0.2^{\circ} 2-\theta$, and $23.3 \pm 0.2^{\circ} 2-\theta$ range into something entirely unknown.” *Supra* at 14. Gilead's proposed construction generates well-defined numerical ranges into which an experimental peak must fall in order to come within the scope of the claim. Using the claimed peak at “about $5.5^{\circ} 2-\theta \pm 0.2^{\circ} 2-\theta$ ” as an example, Gilead's proposed construction reads on an experimental peak position of greater than or equal to $5.3^{\circ} 2-\theta$ but less than or equal to $5.7^{\circ} 2-\theta$, after rounding to the nearest tenth of a degree (i.e., $5.25^{\circ} 2-\theta$ to less than $5.75^{\circ} 2-\theta$). Such a well-defined numerical range of an experimental value is the antithesis of indefiniteness.

4. Defendants' Sur-Reply Position

Gilead's Reply confirms that it seeks revision of the patent claims it received from the Patent Office so that it might ease its infringement burden. In June of 2014, Gilead stated to the Patent Office (and the public) in its original application that “[r]eference to ‘about’ a value or parameter herein includes (and describes) embodiments that are directed to that value or parameter per se.” Ex. 5, 8 ('245 provisional application); *see also* Ex. 1 ('342 Patent), 6:34–36. Gilead also provided an example, stating that a description “referring to ‘about X’ includes [a] description of ‘X’.” *Id.* at 6:35–36. Gilead also chose to write claims using both the defined term “about” and a common and accepted margin of error for the claimed XRPD peaks. It is hard to imagine a more explicit example of a patent specification providing “a special definition given to a claim term by

the patentee that differs from the meaning it would otherwise possess.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (*en banc*), *cert. denied*, 546 U.S. 1170 (2006). Applying this definition, use of “about” in the claim language is meant to include and describe the recited range around the peak positions: “ $\pm 0.2^\circ$ 2- θ .”

Before this Court, Gilead changes course, and proclaims that “about” now should have a different meaning. In an attempt to ease its burden of proving infringement, Gilead urges the Court to redefine “about” as a term that signals to the POSA that the peak positions should be read, in addition to its chosen margin of error ($\pm 0.2^\circ$ 2- θ), to further allow for “*imprecision at the boundaries*” of the claimed margin of error. (*Supra* at 15.) This new-found “*imprecision at the boundaries*” of the claimed margin of error requires additional words directed to *rounding* to be added to the claim language – words the Patent Office did not examine or allow. *Id.* As stated in Defendant’s Responsive Brief, the intrinsic record contains no mention (at all) of accounting for such “*imprecision at the boundaries*” of the claimed margin of error. *Supra* at 15. There is only a chosen margin of error, preceded by “about,” a term that Gilead specifically defined to include (and describe) only “embodiments that are directed to that value or parameter per se.” *See* Ex. 1 (’342 Patent), 6:36–37. Claim construction is not a proper vehicle for trying to use “imprecision” to broaden claim scope when that imprecision is addressed by the express recitations of the claims.

The Defendants’ construction does not advocate for peak ranges that are exact, or are “so infinitely precise,” as Gilead argues. The recited margin of error is itself a common, and well accepted means for addressing the undisputed variability that is inherent in such an analytical technique. *See* Ex. 2, Chyall Decl., ¶ 38 (citing U.S. Pharmacopeia 35, Chapter 941, *X-Ray*

Diffraction (rev. 2011)).⁴ Gilead chose the margin of error, and explained in its specification what it meant by use of the word “about,” not Defendants. And, in the common specification, Gilead elected to report peak positions to a tenth of a degree 2- θ . Ex. 1 (’342 Patent), 23:65–24:20. The claims also were drafted with this same level of precision (to the tenth of a degree 2- θ). Gilead chose not to define the level of precision in the claims to any greater level of detail, such as to a hundredth of a degree, even though it expressly noted that in the specification as an option. Ex. 1 (’342 Patent), 23:56–60. Whether Gilead (when preparing its patent applications) rounded experimental values to arrive at the peak positions it reported in its specification is not relevant. What matters is the level of precision recited in the claims.

Finally, Gilead’s struggle with how one might determine whether an experimentally derived XRPD peak is within the claimed margin of error is not an appropriate topic for claim construction. Claim terms are supposed to be construed before infringement issues are addressed. *Lemelson v. United States*, 752 F.2d 1538, 1549 (Fed. Cir. 1985) (citing *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1569 (Fed. Cir. 1983) (“Proper claim construction necessarily precedes determining whether the claims in suit read on the accused devices.”)). And, there is no canon of claim construction that prefers an “easy to prove infringement” construction. *HSM Portfolio LLC v. Elpida Memory, Inc.*, 160 F.Supp.3d 708, 716, n.5 (D. Del. 2016) (citing *HSM Portfolio LLC v. Fujitsu Ltd.*, 2014 U.S. Dist. LEXIS 81876, at *9–10 (D. Del. June 17, 2014) (Markman order)). Hypothetical difficulties that may arise as Gilead seeks to prove infringement is for another day

⁴ Dr. Chyall, like Dr. Muzzio, is also being compensated for his time, and Defendants believe both expert declarations are helpful, and should be considered. See *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1370–71 (Fed. Cir. 2017) (deferring to the district court’s underlying reliance on expert testimony when construing what a person of ordinary skill would understand “vitamin B12” to mean). After all, “[t]he inquiry into how a person of ordinary skill in the art understands a claim term” is the question at the core of any claim construction – not what litigation counsel may believe patent claim terms mean. *Phillips*, 415 F.3d at 1313.

when all parties have actual data to review. Rhetorical hypotheticals should not serve as a basis for re-writing claim terms that the Patent Office has examined and issued.

**B. “A method for treating an HIV infection in a human in need thereof”
('067 patent: claims 1, 10)**

Gilead’s Proposed Construction	Defendants’ Proposed Construction
Preamble is limiting. “a method for alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load in a human in need thereof.”	Preamble is limiting. “a method for alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load in a human in need thereof, which does not require any particular level of efficacy or any particular level of other therapeutic results.”

1. Plaintiff’s Opening Position

The preamble of claims 1 and 10 of the '067 patent recites “a method for treating an HIV infection in a human in need thereof.” Both parties agree that the preamble is limiting. The parties further agree that this preamble means “a method for alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load in a human in need thereof.” This definition is derived directly from the specification’s definition of “treatment.” See '067 patent at 5:21–24. That should be the end of the matter. But Defendants propose adding an additional qualification, found nowhere in the specification, that such a method “does not require any particular level of efficacy or any particular level of other therapeutic results.” Defendants’ proposal is contrary to the governing principles of claim construction, and it results in a construction that is internally inconsistent, inconsistent with the specification, and inconsistent with the rest of the claim.

**a. Defendants’ Proposed Construction Adds a Limitation Not
“From the Specification**

The shared portion of Plaintiff’s and Defendants’ proposed constructions, “a method for alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load in a human

in need thereof,” is lifted directly from the specification’s definition of the term “treatment.” ’067 patent at 5:21–24. The specification’s definition of the term “treatment,” which is consistent with how a POSA would understand the plain and ordinary meaning of that term, should begin and end the inquiry into the appropriate construction of this claim term.

But Defendants’ proposal goes beyond the specification’s definition and imports an additional limitation further qualifying that definition: “which does not require any particular level of efficacy or any particular level of other therapeutic results.” That language is found nowhere in the specification (indeed, nowhere in the patent). This fact alone demonstrates that Defendants’ proposed construction is legally improper and unsupported. “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Defendants’ proposed construction is nothing more than “added language without support from the specification or prosecution history, altering otherwise unambiguous claim language, a practice [the Federal Circuit] has repeatedly rejected.” *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1299 (Fed. Cir. 2014).

b. Defendants’ Proposed Construction Is Inconsistent With Itself and With the Specification

The fundamental flaw with Defendants’ proposal is that it is inconsistent with the specification’s definition of “treatment” and results in an internally inconsistent claim construction. Defendants’ construction adds the qualifier that the method “does not require any particular level of efficacy or any particular level of other therapeutic results.” But that cannot be true, because a treatment that “alleviate[s] or eliminate[s] symptom of HIV infection and/or [] reduce[s] viral load in a patient” is a treatment that has a particular level of efficacy and a particular

level of therapeutic results—it must alleviate or eliminate symptoms of HIV infection and/or reduce viral load in the patient. In other words, it must be an effective treatment. It would make no sense to say a method “alleviate[s] or eliminate[s] symptom of HIV infection and/or [] reduce[s] viral load in a patient,” but can, in fact, be ineffective in treating a patient’s HIV infection.

The necessary consequence of Defendants’ construction is that “a method for treating an HIV infection in a human in need thereof” requires only the *intention* to treat HIV—such a method need not *actually* “alleviat[e] or eliminat[e] symptoms of an HIV infection” or “reduc[e] HIV viral load.” That would mean, in Defendants’ world, bloodletting and hypnosis are both “a method for treating an HIV infection in a human in need thereof,” so long as they are performed with the purpose of “alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load in a human in need thereof.” Such a result is not only nonsensical but internally inconsistent, in that the second clause of Defendants’ proposed construction (which encompasses a method of treatment having no efficacy) is at odds with the first (which requires the method be efficacious).

In the same vein, Defendants’ proposed construction is inconsistent with the specification of the ’067 patent. For example, the specification explains that the “goal of antiretroviral therapy,” which is administered for the “treatment of HIV infected patients,” is “achiev[ing] viral suppression in the HIV infected patient.” ’067 patent at 1:37–51. And the specification defines “human (or patient) in need thereof” as “a human who may have or is suspect to have diseases or conditions that would *benefit* from certain treatment; for example, being treated with the compounds disclosed herein according to the present application.” ’067 patent at 6:15–19. A “method for treating” that was intended as a treatment for an HIV infection, but did not reach the level of being an *effective* treatment of an HIV infection, would provide no “benefit” at all to a person in need thereof. Broadly, the specification’s extensive discussion of the concept of

“treatment” would make little sense if a method could be “a method for treating an HIV infection” despite not being an effective treatment.

Defendants’ proposed construction is also inconsistent with the views of the Patent Office during prosecution of the ’067 patent. Early in the prosecution of the application that led to the ’067 patent, the Patent Office required the applicant to elect between then-pending “[c]laims 1-24, drawn to a compound of Formula II” (Invention I) and “[c]laim 25, drawn to a method of treating or prophylactically preventing HIV infection” (Invention II). *See* Ex. 9, BICANDA00000106 at - 334. In justifying the Restriction Requirement, the examiner stated that

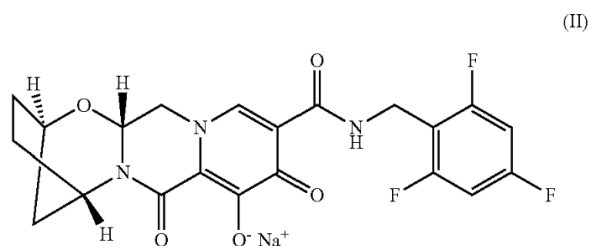
Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. *See* MPEP § 806.05(h). In the instant case abacavir [a nucleoside reverse-transcriptase inhibitor, also used to treat HIV] can be used to treat HIV infection.

Id. The examiner’s reasoning makes sense provided that the examiner understood, consistent with Plaintiff’s proposed construction, that “a method for treating an HIV infection” requires it be an effective treatment—the examiner’s identification of abacavir as another compound that “can be used to treat HIV infection” was clearly premised on an understanding that compounds which “can be used to treat HIV infection” must be effective in doing so. On the other hand, if Defendants’ proposed construction were correct, the examiner’s identification of abacavir would be gratuitous and unnecessary, because under Defendants’ proposed construction, *anything* could be administered as “a method for treating an HIV infection,” provided it is administered for that purpose. The examiner may as well have identified Epsom salts, or orange juice.

c. Defendants' Proposed Construction Is Inconsistent With the Rest of the Claim

In addition to being inconsistent with itself and with the specification, Defendants' proposal is inconsistent with the overall structure of the claims in which the term appears. For example, claim 1 of the '067 patent reads:

A method for treating an HIV infection in a human in need thereof, comprising administering to the human a therapeutically effective amount of a compound of Formula II:



which is crystalline and is characterized by an x-ray powder diffraction (XRPD) pattern having peaks at about 5.5°, 16.1°, and 23.3° 2-θ±0.2°±2-θ.

'067 patent at 33:8–26. Like “treatment,” “therapeutically effective amount” is defined in the specification. '067 patent at 4:66–5:20. Consistent with that definition, the parties have agreed that “therapeutically effective amount” means “an amount of the claimed compound, which when administered to a patient in need thereof, is sufficient to effect treatment for disease-states, conditions, or disorders for which the compounds have utility.”

Combining Defendants' proposed construction of “a method for treating an HIV infection in a human in need thereof” with the agreed construction of “therapeutically effective amount” results in the following:

Claim Term	Claim Construction under Defendants' Proposal
A method for treating an HIV infection in a human in need thereof, comprising administering to the human a therapeutically effective amount...	A method for alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load in a human in need thereof, <u>which does not require any particular level of efficacy or any particular level of other therapeutic results,</u> comprising administering to the human an amount of the claimed compound, <u>which when administered to a patient in need thereof, is sufficient to effect treatment for disease-states, conditions, or disorders for which the compounds have utility...</u>

The underlined portions of the resulting construction demonstrate the inconsistency that Defendants' proposed construction creates. Defendants propose that "a method for treating an HIV infection in a human in need thereof" "does not require any particular level of efficacy or any particular level of other therapeutic results." But the *agreed construction* of the very next phrase in the claim, "therapeutically effective amount," specifies a required degree of efficacy—the method for treating, which comprises "administering to the human an amount of the claimed compound [*i.e.* bictegravir sodium]," must be "*sufficient to effect treatment* for disease-states, conditions, or disorders for which the compounds have utility." Again, as the preamble already makes clear, the treatment must be efficacious in that it must be an effective treatment for an HIV infection. The result of combining Defendants' proposed construction with the parties' agreed construction is a paradoxical method for treating an HIV infection that does not require any particular level of efficacy, but nonetheless must reach the particular level of efficacy that it is effective in treating an HIV infection.

The Court should reject Defendants' proposed construction and adopt Plaintiff's proposed construction.

2. Defendants' Answering Position

a. The Intrinsic Evidence Supports Defendants' Construction

As noted by Gilead, the '067 Patent claims recite “[a] method for treating an HIV infection in a human in need thereof” (Claims 1, 10) and the parties agree that this preamble is limiting. Thus, the crux of the dispute between the parties is what “treating” means.

As discussed in more detail below, both the '067 Patent claims and specification make clear that there is no particular, specific benchmark of efficacy that must be achieved in order for the '067 Patent claims to be met. Moreover, the specification expressly discloses that “treating” an HIV infection can take many forms. Thus, the claims “do not require any particular level of efficacy or any particular level of other therapeutic results,” and Defendants' construction is correct.

Claims. The '067 Patent claims do not recite any efficacy limitations. For example, the claims do not require that viral load^{5,6} be reduced below a particular value, nor do they require that viral load be reduced by a certain percent. They also do not require that a particular symptom must be reduced by any particular degree. In other words, although specifically defined efficacy

⁵ “Viral load is the quantity of viral RNA in a given volume expressed as infectious particles per milliliter.” Ex. 6 (Santosh Shenoy, “SARS-CoV-2 (COVID-19), viral load and clinical outcomes; lessons learned one year into the pandemic: A systematic review,” 10(4) WORLD J. CRITICAL CARE MED. 132–50, 143 (2021); *see also* Ex. 7 (DEPARTMENT OF HEALTH & HUMAN SERVICES (DHHS) PANEL ON ANTIRETROVIRAL GUIDELINES FOR ADULTS AND ADOLESCENTS – A WORKING GROUP OF THE OFFICE OF AIDS RESEARCH ADVISORY COUNCIL (OARAC), GUIDELINES FOR THE USE OF ANTIRETROVIRAL AGENTS IN HIV-1-INFECTED ADULTS AND ADOLESCENTS at C-5) at DEFS_BIC_00001023 (“Thus, viral load testing is an established surrogate marker for treatment response. The minimal change in viral load considered to be statistically significant (2 standard deviations) is a three-fold change (equivalent to a 0.5 log₁₀ copies/mL change).”).

⁶ Methods developed for accurate quantification of viral load by the priority date of the '067 Patent included “quantitative competitive polymerase chain reaction (QCPCR), nucleic acid- based sequence amplification (NASBA), branched-chain DNA (b-DNA), and the Amplicor microwell plate assay.” Ex. 8 (Thomas Merigan, “Individualization of Therapy Using Viral Markers”, 10 (Suppl. I) J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES AND HUMAN RETROVIROLOGY S41–S46, S43 (1995)).

benchmarks are well known in the pharmaceutical field, the patentees here elected not to include them in the claims. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1368–69 (Fed. Cir. 2023) *cert. denied*, 144 S. Ct. 873, 218 L. Ed. 2d 59 (2024) (upholding District of Delaware’s construction of “treating pulmonary hypertension” as not requiring a showing of safety or efficacy because no safety and efficacy requirements appeared in the claims); *cf.*, *Galderma Lab’ys, L.P. v. Teva Pharms, USA, Inc.*, 799 F. App’x 838, 840 (Fed. Cir. 2020) (“The claims also recite certain efficacy benchmarks resulting from the treatment methods. These benchmarks measure certain parameters, including: (1) lesion count reduction, *i.e.*, the difference in the number of inflammatory lesions before and after treatment; (2) Investigator’s Global Assessment (“IGA”) success rate []; and, (3) relapse-free time”).

Gilead points out that the ’067 Patent claims require administration of “a therapeutically effective amount” of a drug (bictegravir sodium characterized by specific peaks)⁷ to a human and argues that Defendants’ construction is inconsistent with the joint proposed construction for “therapeutically effective amount.” *E.g.*, *supra* at 27–28; *see also id.* at 25–26. This argument fails because the claims do not specify what a therapeutically effective amount is, and the joint proposed construction for “therapeutically effective amount” simply states that the amount is “sufficient to effect treatment for disease-states, conditions, or disorders for which the compounds have utility,” which is what is expressly stated in the specification. Ex. 1 (’342 Patent), 5:1–5. As such, far from supporting Gilead’s point, the “therapeutically effective amount” construction simply highlights that what constitutes “treatment” is at the heart of the dispute. Moreover, what

⁷ Given that the claims expressly require administration of bictegravir sodium, Gilead’s argument that “under Defendants’ proposed construction, *anything* could be administered as ‘a method for treating an HIV infection’” (*supra* at 27) and that “in Defendants’ world, bloodletting and hypnosis are both ‘a method for treating an HIV infection in a human in need thereof’” (*id.* at 25) are nonsensical.

is sufficient to “effect treatment” is left wholly unlimited by the claim language. Thus, Gilead’s argument that Defendants’ construction is at odds with the joint construction of “therapeutically effective amount” is incorrect.

Specification: The specification supports Defendants’ construction, not Gilead’s.

Therapeutically Effective Amount. Underscoring that no pre-set benchmark must be achieved to satisfy the requirements of the claims, the specification expressly teaches that what constitutes a therapeutically effective amount “*var[ies]* depending on a variety of factors,” including the severity of the particular disorder or condition, and the subject undergoing therapy:

The compounds disclosed herein are administered in a ***therapeutically effective amount, which will vary depending upon a variety of factors*** including the...general health, sex, and diet of the patient; the mode and time of administration; the rate of excretion; the drug combination; the severity of the particular disorder or condition; and the subject undergoing therapy.

Ex. 3 (’067 Patent), 13:6–14 (emphasis added).

Treatment. The specification contains multiple disclosures of various types of “treatment” encompassed by the claims, which is exactly what is captured by Defendants’ phrase “which does not require any particular level of efficacy or any particular level of other therapeutic results.” See *id.* at 5:22–61.

The specification first discloses that the term “treatment” means alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load, as stated in both parties’ constructions. However, the specification ***also*** states that definition only applies to “certain embodiments.”

In certain embodiments, the term “treatment” as used herein is intended to mean the administration of a compound or composition according to the present invention to alleviate or eliminate symptoms of HIV infection and/or to reduce viral load in a patient.

Ex. 3 ('067 Patent), 5:36–41 (emphasis added). The specification goes on to explicitly state that the term “treatment” “also encompasses” administration of the compound for multiple types of prevention,⁸ as well as maintenance of an already reduced or low viral load. More specifically, the specification states that the following diverse situations constitute “treatment,” none of which require “any particular level of efficacy or any particular level of other therapeutic results,” just as Defendants contend:

- i. “post-exposure of the individual to the virus but ***before the appearance of symptoms of the disease***, and/or prior to the detection of the virus in the blood, ***to prevent the appearance of symptoms of the disease and/or to prevent the virus from reaching detectable levels in the blood***”;
- ii. “to ***prevent perinatal transmission*** of HIV from mother to baby, by administration to the mother before giving birth and to the child within the first days of life”;
- iii. “to ***maintain a reduced viral load*** in a patient; and
- iv. post-exposure of the individual to the virus as a subsequent or additional therapy to a first-line therapy (e.g., for ***maintenance of low viral load***).

Ex. 3 ('067 Patent), 5:28–29; 5:34–36; 5:44–45; 5:60–62 (emphasis added). These represent “treatments” for which the claimed compounds also have utility and are also covered by the parties’ stipulated construction for “therapeutically effective amount.” *Id.* at 5:63–6:4.

The portions of the specification cited by Gilead further prove Defendants’ point. For example, Gilead relies on the phrase “achiev[ing] viral ***suppression*** in the HIV infected patient.” So “viral suppression” in an infected patient is yet another result that Gilead admits is part of “treating” HIV, yet “suppression” requires no particular measurement of reduction of viral load.

⁸ The specification also defines prevention: “‘Prevention’ or ‘preventing’ means any treatment of a disease or condition that causes the clinical symptoms of the disease or condition not to develop. The term ‘prevention’ also encompasses the administration of a compound or composition according to the present invention pre-exposure of the individual to the virus (e.g., pre-exposure prophylaxis), to prevent the appearance of symptoms of the disease and/or to prevent the virus from reaching detectable levels in the blood.” Ex. 2 ('067 Patent), 5:63–6:4.

See supra at 25–26 (citing ’067 Patent at 1:37–51). Similarly, Gilead’s statement that “the specification defines ‘human (or patient) in need thereof’ as ‘a human who may have or is suspect [sic] to have diseases or conditions that would benefit from certain treatment[.]’” (*id.* at 13) suffers from the same flaw. Specifically, it fails to recognize that a human who only “may have” or is “suspected” to have a HIV infection may require different treatment effects/results than a person with a severe HIV infection. And if that severely infected patient was carrying a child, the infected mother will require different treatment effects/results than her baby to whom transmission is being prevented. As discussed above, the specification teaches that what constitutes “a therapeutically effective amount...will vary depending upon a variety of factors including the...general health, sex, and diet of the patient...the severity of the particular disorder or condition; and the subject undergoing therapy.”). Ex. 3 (’067 Patent), 13:6–14. This further confirms that the claims do not require any particular benchmark, any particular level of efficacy or therapeutic result, to qualify as treatment.

In sum, the specification expressly teaches that treatment encompasses administration of bictegravir sodium in a variety of situations, for which the claims do not require specific baseline measurements. Thus, the specification confirms that no particular level of efficacy or other therapeutic is required by the claims.⁹

Prosecution History. The prosecution history contains various references to “treatment” that do not include any particular efficacy benchmarks. Further, the prosecution history does not define “treatment” or “therapeutically effective amount” more narrowly than the specification—

⁹ There are various other references to “treatment” in the specification, none of which include any references to particular efficacy benchmarks. *See* Ex. 2 (’067 Patent), 2:55; 2:64; 3:3; 5:2; 5:12; 5:13; 6:6; 6:17; 6:18; 10:2; 12:50; 13:21; 13:28; 13:35; 13:43; 13:48; 13:52; 13:57; 13:59; 13:65; 14:5; 14:6; 14:8; 14:10; 14:16; 14:21; 14:24; 14:30; 14:37–38; 14:40; 14:43; 15:11; 15:66; 16:10; 16:12; 16:19; 17:23; 19:66; 25:60; 26:13–15.

indeed, it does not define these terms at all. *See* Ex. 9 ('067 Patent Prosecution History Excerpts) at BICANDA00000195–201 (October 26, 2017 Preliminary Amendment at 2–5 (Claims)); *id.* at BICANDA00000343–349 (March 15, 2018 Amendment at 2–5 (Claims) and Amendment Remarks (6–7)); *id.* at BICANDA00000332–340 (January 16, 2018 Requirement for Restriction/Election); *id.* at BICANDA00000343–354 (March 15, 2018 Response to Election/Restriction); *id.* at BICANDA00000355–366 (April 23, 2018 Ex Parte Quayle Action); *id.* at BICANDA000003711–3713, BICANDA000004335–4348 (August 2, 2018 Response After Ex Parte Quayle). Therefore, the prosecution history supports Defendants' construction.

In summary, Defendants' construction captures: (i) the fact that the '067 Patent claims do not require any particular benchmarks of efficacy or other therapeutic result; (ii) the specification's multiple express disclosures that "treatment" may take many forms, including prevention and maintenance, none requiring specific measurements; and (iii) the parties' joint construction of "therapeutically effective amount." Defendants' construction is correct based on the intrinsic evidence, and Defendants respectfully request that the Court adopt it.

b. Gilead's Arguments Ignore the Intrinsic Evidence and Lack True Substance

Gilead makes theatrical arguments in opposing Defendants' construction—*e.g.*, that "in Defendants' world, bloodletting and hypnosis are both 'a method for treating an HIV infection in a human in need thereof.'" *Supra* at 25. Gilead's arguments ignore the intrinsic evidence, including the bictgravir sodium form required by the claims, and appear to be an attempt to hide a lack of substance in an abundance of style. Indeed, Gilead includes only two sentences to argue in favor of its own construction. *See supra* at 23 ("This definition is derived directly from the specification's definition of 'treatment.' That should be the end of the matter."). But as discussed

below, these statements are only possible because Gilead ignores large portions of the specification, and Gilead's arguments must fail.

Claims. Gilead ignores that the claims do not recite any particular level of efficacy or required results and instead argues that Defendants' construction is inconsistent with the joint construction for "therapeutically effective amount." *See generally supra* at 27–29; *id.* at 28 ("Defendants propose that 'a method for treating an HIV infection in a human in need thereof' 'does not require any particular level of efficacy or any particular level of other therapeutic results.' But the *agreed construction* of the very next phrase in the claim, 'therapeutically effective amount,' specifies a required degree of efficacy...."). As discussed in more detail *supra* at 31–33, Gilead's accusations of inconsistency are meritless because the specification expressly teaches that the "therapeutically effective amount" varies depending on a variety of factors, including the severity of disease, and the subject undergoing therapy. Ex. 3 ('067 Patent), 13:6–14.

Further, Gilead's "inconsistency argument" is based on the false premise that the agreed construction for "therapeutically effective amount" "specifies a required degree of efficacy." *Supra* at 28; *see also id.* at 25 (arguing that a treatment that alleviates or eliminates symptom of HIV infection and/or reduces viral load in a patient "is a treatment that has a particular level of efficacy and a particular level of therapeutic results."). But contrary to Gilead's arguments, and as explained *supra* (pp. 10–13), the specification makes clear that there are various disparate HIV-related conditions that that may require treatment and that can vary in severity—and thus, it is evident that there is no specific pre-set benchmark of efficacy. Indeed, to "alleviate or eliminate symptoms of HIV infection and/or reduce viral load in the patient" is a ***general effect*** that is not bounded by ***specific measurements*** of symptom improvement or changes in viral load.

Specification. As for the specification, Gilead cherry-picks the three lines of it that match the shared portion of the parties’ proposed constructions and asserts that that its construction is “derived directly from the specification’s definition of ‘treatment.’” *Supra* at 23 (citing ’067 Patent, 5:21–24); *see also id.* at 24 (arguing that “Defendants’ Proposed Construction Adds a Limitation Not from the Specification,” and citing the same three lines).¹⁰

But Gilead wholly ignores the rest of the relevant text, which, as discussed above, describes the various types for which the claimed compound has utility, as allowed by the joint construction of “therapeutically effective amount.” *See* Ex. 3 (’067 Patent), 5:21–61. Thus, while Gilead is correct that “the specification ‘is always highly relevant to the claim construction analysis” (*Supra* at 24 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005))), the specification here supports Defendants’ construction for the reasons explained above.

Gilead’s attempt to limit the construction of the “treating” term to particular embodiments by cherry-picking three lines from the specification and ignoring the rest should not be countenanced.

Prosecution History. Gilead argues that during prosecution, the examiner required the applicants to choose between claims to the bictegravir compound and claims to a method of treating using the bictegravir compound. *See supra* at 26 (citing Restriction Requirement):

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. *See* MPEP § 806.05(h). In the instant case abacavir [a nucleoside reverse-transcriptase inhibitor, also used to treat HIV] can be used to treat HIV infection.

¹⁰ Curiously, Gilead later refers to “the specification’s extensive discussion of the concept of ‘treatment’” (*Supra* at 26) but again fails to cite to the text in column 5. *See generally* Ex. 2 (’067 Patent), 5:21–61.

Gilead then confusingly argues that “the examiner’s identification of abacavir as another compound that “can be used to treat HIV infection” was clearly premised on an understanding that compounds which “can be used to treat HIV infection” must be effective in doing so.” *Id.*¹¹

This is, to put it mildly, speculative bootstrapping. The examiner did not explain why he invoked abacavir despite the fact that all of the claims-at-issue concerned bictegravir; indeed, the above snapshotted quote captures the only time abacavir was mentioned in the Restriction Requirement whatsoever. As such, it is entirely unclear why the examiner mentioned abacavir, and Gilead’s argument that the statement “was clearly premised on an understanding that compounds which “can be used to treat HIV infection” must be effective in doing so” is rank speculation. Indeed, the only thing clear from the prosecution history is that it does not support Gilead’s attempt to insert specifically defined efficacy benchmarks into the ’067 Patent claims.

Gilead’s Other Arguments. Gilead also mischaracterizes Defendants’ proposed construction as “encompass[ing] a method of treatment having no efficacy.” *Id.* Not so. As explained above, Defendants’ construction simply reflects that there is no ***particular, specific*** benchmark of efficacy or therapeutic result required by the claims. As such, all of Gilead’s arguments invoking the necessity of an effective treatment miss the point. *See, e.g., supra* at 25 (“In other words, it must be an effective treatment.”); *id.* at 26 (“A “method for treating” that was intended as a treatment for an HIV infection but did not reach the level of being an *effective* treatment of an HIV infection, would provide no “benefit” at all to a person in need thereof.”); *id.*

¹¹ Gilead then argues that “if Defendants’ proposed construction were correct, the examiner’s identification of abacavir would be gratuitous and unnecessary, because under Defendants’ proposed construction, *anything* could be administered as “a method for treating an HIV infection,” provided it is administered for that purpose. The examiner may as well have identified Epsom salts, or orange juice.” *Supra* at 27. As noted above, this is nonsensical given that the claims require administration of bictegravir.

(“Broadly, the specification’s extensive discussion of the concept of “treatment” would make little sense if a method could be “a method for treating an HIV infection” despite not being an effective treatment.”); *id.* at 28 (“Again, as the preamble already makes clear, the treatment must be efficacious in that it must be an effective treatment for an HIV infection.”).

For at least the above reasons, the Court should construe “[a] method for treating an HIV infection in a human in need thereof” as: “a method for alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load in a human in need thereof, which does not require any particular level of efficacy or any particular level of other therapeutic results.”

3. Plaintiff’s Reply Position

The core problem with Defendants’ construction is that it includes an additional limitation, “which does not require any particular level of efficacy or any particular level of therapeutic results,” that is neither found in the patent’s discussion of the meaning of treat[ing], nor anywhere else in the specification. It is also at odds with the parties’ agreed construction of “therapeutically effective amount.” Furthermore, Defendants argue that the claims of the ’067 patent do not specify numeric or quantitative efficacy benchmarks, but that argumentation and the phrasing of their proposed construction must mean those claims do not require *any* efficacy in “treating an HIV infection.” This proposed construction deprives “a method for treating an HIV infection” of its plain and ordinary meaning to a POSA and renders the claim almost nonsensical.

a. Defendants Add a Limitation Found Nowhere in the Patent That Is at Odds With the Rest of the Construction

Defendants’ construction mimics Gilead’s, except for the addition of “which does not require any particular level of efficacy or any particular level of other therapeutic results.” But that limitation is an addition found nowhere in the patent. The patent defines treatment as “intended to mean the administration of a compound or composition according to the present invention to

alleviate or eliminate symptoms of HIV infection and/or to reduce viral load in a patient.” ’067 patent at 5:20–24. The patent’s definition does not go on to add Defendants’ additional clause. Nor could it. That clause is found nowhere in the patent.

Despite their construction having no basis in the patent, Defendants accuse Gilead of cherry-picking. *Supra* at 36. But Gilead’s construction is not only consistent with the *definition* of treatment in the specification, it is consistent with the patent as a whole. “[T]he ‘ordinary meaning’ of a claim term is its meaning to the ordinary artisan *after reading the entire patent*.” *Phillips*, 415 F.3d at 1321 (emphasis added). This is a patent *about treating HIV*. ’067 patent at 1:37–51 (“A goal of antiretroviral therapy is to achieve viral suppression in the HIV infected patient.”); *see also id.* at 4:66–5:6, 21:34–65, Other Publications. It is Defendants who have cherry-picked, adding an invented limitation to serve some litigation-driven position and asking this Court to believe that a method for treating HIV allows a lack of any efficacy at all.

In addition to the claim term in dispute, the claims separately require administration of “a therapeutically effective amount” of bictegravir sodium. The parties have agreed upon a construction of that term, taken directly from the patent specification. But Defendants’ proposed construction of “method for treating” is inconsistent with the parties’ agreed construction. A “therapeutically effective amount” means “an amount of the claimed compound, which when administered to a patient in need thereof, is *sufficient to effect treatment* for disease-states, conditions, or disorders for which the compounds have utility.” (emphasis added). Defendants nonetheless argue that the agreed construction does not “specif[y] a required degree of efficacy” or set a “specific pre-set benchmark of efficacy.” *Supra* at 36. In Defendants’ view, a method that is “sufficient to effect treatment” need not actually be sufficient to do anything in particular. Their

interpretation cannot be correct. Rather, the specification explains in detail the clinical outcomes that constitute HIV treatment (and what is “sufficient to effect treatment”).

Defendants repeatedly emphasize that the amount (i.e., the dosage) of bictegravir sodium which constitutes a “therapeutically effective amount” may vary based on a variety of factors, including the patient themselves, their general health, sex, and diet, etc. *See supra.* at 30-33. But this does not suggest that a “method for treating an HIV infection” need not be efficacious—merely that the *dose* of bictegravir sufficient to affect this treatment may vary. The patent identifies a range of doses of bictegravir sodium that may constitute a “therapeutically effective amount” in various situations and for various patients. *See* ’067 patent at 10:15–34. So long as the dosage is a “therapeutically effective amount,” neither the claims nor Gilead’s proposed construction require any specific dosage or suggest that the amount which is “therapeutically effective” cannot vary.

b. Defendants’ Proposed Construction Does Not Clarify the Claim Term

What constitutes treatment for HIV is well understood in the art. In fact, it is undisputed. A physician who treats HIV knows what constitutes treating HIV and knows what constitutes alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load. The patent and its claims do not exist in a vacuum. The ’067 patent concerns “therapeutic compositions for treatment of human immunodeficiency virus” [HIV], including methods of using such compositions.¹² A physician would similarly understand that a “viral load” is the amount of HIV

¹² As another example, the patent states that “[a] goal of antiretroviral therapy is to achieve viral suppression in the HIV infected patient.” Ex. 3, ’067 patent at 1:37-38. Defendants quibble with the understanding of viral suppression, a term of art in HIV. But a POSA would understand it. *See* CDC, *HIV Treatment as Prevention*, <https://www.cdc.gov/hiv/risk/art/index.html> (last accessed Oct. 31, 2024). A similar term is used in conjunction with clinical studies of HIV, including Gilead’s bictegravir trials. *See* <https://www.biktarvy.com/about-biktarvy/efficacy-effectiveness> (last accessed Oct. 31, 2024). And a similar term (“virologically suppressed”) is used in Defendants’ own ANDAs. *See* LRS-

in a person's blood.¹³ A viral load can be measured and tracked. So can a reduction in it. A physician similarly understands what it means to alleviate symptoms of HIV. HIV infection comes with physical manifestations, such as fever, aches, pains, chills, and other symptoms. Reducing the physical toll of those symptoms is alleviating those symptoms.¹⁴

Therefore, Defendants cannot plausibly allege that a POSA would be confused by what constitutes "alleviating or eliminating symptoms of an HIV infection" or "reducing HIV viral load." But if a POSA were confused about the meaning of either of those phrases, Defendants' additional limitation would be of no help. Defendants' proposal does not further explain treating, alleviating or eliminating symptoms, or reducing HIV viral load. In fact, Defendants' additional limitation creates more confusion by suggesting that any level of efficacy (even zero) would be considered treating an HIV patient in 2014. This is yet more evidence that the goal of Defendants' construction is not to define the boundaries of the claim, but to get some yet-to-be-understood litigation benefit through their construction.

Defendants ultimately equivocate that their construction "reflects that there is no *particular, specific* benchmark of efficacy or therapeutic results required by the claims." *Supra* at 37 (emphasis Defendants'). Defendants thus concede that the claims require some (non-particular, non-specific) benchmark of efficacy or therapeutic results that is greater than zero, but they do not

BCT-0000170 (Laurus prescribing information); CIP-BCT-0076615 at -617 (Cipla prescribing information); LUPIN_BIKTARVY_00049922 at -924 (Lupin prescribing information).

¹³ MedLine Plus (National Library of Medicine), *HIV Viral Load*, <https://medlineplus.gov/lab-tests/hiv-viral-load/> (last accessed Oct. 31, 2024).

¹⁴ See U.S. Dept. of Health & Human Services, HIV.gov, <https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/symptoms-of-hiv> (last accessed Oct. 31, 2024).

explain how their proposed construction could be consistent with such a requirement. It is not and should therefore be rejected.¹⁵

c. The Intrinsic Evidence of “Treating” That Defendants Cite Supports Gilead

Treating HIV may take a variety of forms and yield a variety of results. Defendants quote four examples of HIV treatment from the specification that they argue support their view that a limitation regarding a lack of an efficacy requirement should be added to the claim language:

- “post-exposure of the individual to the virus but before the appearance of symptoms of the disease, and/or prior to the detection of the virus in the blood, *to prevent the appearance of symptoms of the disease and/or to prevent the virus from reaching detectable levels in the blood*”;
- “*to prevent perinatal transmission of HIV from mother to baby, by administration to the mother before giving birth and to the child within the first days of life*”;
- “*to maintain a reduced viral load in a patient*,” and
- “post-exposure of the individual to the virus as a subsequent or additional therapy to a first-line therapy (e.g., for *maintenance of low viral load*).”

Supra at 32 (citing ’067 patent at 5:28–29, 5:34–36, 5:44–45, 5:60–62) (emphases added). While these examples don’t specify quantitative or numerical metrics of efficacy, they do specify clinical outcomes¹⁶ that are achieved upon effective treatment. Far from not requiring “any particular level

¹⁵ Defendants’ proposed construction and briefing are at odds with one another. The construction that would actually be consistent with Defendants’ briefed position is: “a method for alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load in a human in need thereof, which *requires a greater-than-zero improvement* in alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load.”

¹⁶ Defendants refer to the specification’s discussion of “prevention” (called “pre-exposure prophylaxis” or “PrEP”) as a form of treatment. *See, e.g., supra* at 32 n.9. While this form of treatment is discussed in connection with clinical outcomes, it does not bear on the construction of these claims, because they require “[a] method for *treating an HIV infection* in a human in need thereof.” Patients on prevention definitionally do not have “an HIV infection.”

of other therapeutic results,” these examples of HIV treatment articulate *specific therapeutic results* that are required to constitute treatment.

Moreover, as Defendants repeatedly point out, the claims require administration of bictegravir sodium, a compound known to be efficacious in treating HIV. A POSA would know how to evaluate whether the administered treatment “prevent[ed] the appearance of symptoms” of HIV or “prevent[ed] perinatal transmission of HIV from mother to baby.” In the case of “maintain[ing] a reduced viral load,” Defendants’ claim that “[viral] suppression’ requires no particular measurement of reduction of viral load,” *supra* at 33, is flatly wrong. A POSA would understand that this is a clinical outcome evaluated by a quantitative measurement. *See supra* at 41 n.13. The claim should be construed in accordance with a POSA’s understanding of what constitutes “treating an HIV infection.”

Defendants rely on *United Therapeutics*, but the Federal Circuit’s holding in *United Therapeutics* does not support Defendants, and in fact confirms Gilead’s position.¹⁷ The claim at issue in that case recited “[a] method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of” the claimed compound. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1364 (Fed. Cir. 2023), *cert. denied*, 144 S. Ct. 873 (2024). The construction of “therapeutically effective single dose,” unchallenged on appeal, was “a dose given in a single treatment session that causes an improvement in a patient’s hemodynamics (reduced PAP or PVR).” *Id.* at 1369. On appeal, the Federal Circuit held only that “[r]ead in context” with the

¹⁷ Defendants also cite *Galderma Laboratories*, which is irrelevant. *See supra* at 30. There, the claims recited specific, quantifiable measurements of efficacy, such as scores on a clinical scoring scale and relapse-free time. *Galderma Lab’ys, L.P. v. Teva Pharms. USA, Inc.*, 799 F. App’x 838, 840 (Fed. Cir. 2020). There is no dispute that the claims at issue here were not drafted in this manner.

unchallenged construction of “therapeutically effective single dose,” the term “treating pulmonary hypertension” did not “import any *additional* efficacy limitations or any safety limitations.” *Id.* (emphasis added). That reasoning is consistent with Gilead’s position, which adds no additional efficacy limitations. It is Defendants who have added additional limitations specific to efficacy.

The specification discusses different types of clinical outcome associated with HIV treatment depending on the patient. There is nothing about these outcomes, which a POSA would understand how to identify and evaluate, that make a “method for treating for an HIV infection” unclear.

4. Defendants’ Sur-Reply Position

Gilead seems to agree that the claims do not recite any specific quantitative measure of efficacy, and with the premise that different HIV patients have different needs and will likely exhibit different results. It also does not argue that the recited “method of treating” requires an external validator, such as FDA approval. However, Gilead’s arguments show that it is reading some embodiments out the claims (for an unknown reason).¹⁸ Moreover, its tardy appeal to plain and ordinary meaning is misplaced; plus, that supposed plain and ordinary meaning conflicts with the specification.

a. The Parties Agree the Claims Do Not Require a Quantitative Measure of Efficacy, and Gilead’s “Clinical Outcomes” Argument Excludes Various Embodiments

Gilead concedes the claims do not recite any specific quantitative measure of efficacy. *Supra* at 43. Instead, Gilead argues that “[w]hile these examples don’t specify quantitative or

¹⁸ Perhaps Gilead is attempting to adhere to the indications of the commercial embodiment (Biktarvy®), but if so, that is misplaced because it is black-letter law that claims are not construed to match the commercial embodiment. *See, e.g. Myco Industries, Inc. v. BlephEx, LLC*, 955 F.3d 1, 15 (Fed. Cir. 2020) (“[C]laim construction, from which an infringement analysis depends, focuses on the recited limitations of the claims, not on the features of a commercial embodiment of the invention.”).

numerical metrics of efficacy, they do specify clinical outcomes that are achieved upon effective treatment.” *Id.* Nothing in Defendants’ construction would exclude clinical outcomes that might be achieved upon completion of an effective treatment, particularly given how the term is expansively defined in column 5 of the specification. What Gilead fails to recognize is that there must be some allowance for various clinical outcomes. For example, an individual with a suppressed and undetectable level of viral load would, after treatment to continue suppression, still have an undetectable viral load. An individual treated to prevent the onset of symptoms would, after treatment, still have no symptoms. And so forth. As discussed below, none of these or similar treatment outcomes are captured by Gilead’s construction despite being explicitly listed as embodiments of the invention. Ex. 3 (’067 Patent), 5:24–61. Thus, Gilead’s construction is incomplete; only Defendants’ construction captures the full scope of the invention as described in the specification.

b. Gilead’s Construction Ignores the Vast Majority of the Specification’s Column 5

No one disputes that the agreed portion of the parties’ constructions comes directly from ~4.5 lines of the patent. Ex. 3 (’067 Patent), 5:20–24. But, as Defendants explained in detail in their Responsive Brief, Gilead’s construction fails because it ignores the next 37 lines of the specification, which explain and expand the definition of “treatment.” *Id.* at 5:24–61. The specification goes beyond simply “eliminating symptoms of an HIV infection and/or reducing HIV viral load” to include, among other things, “prevent[ing] perinatal transmission of HIV from mother to baby,” “prevent[ing] the appearance of symptoms of the disease and/or to prevent the virus from reaching detectable levels in the blood,” and “maintain[ing] a reduced viral load in a patient.” *Id.* at 5:28–29, 5:34–36, 5:44–45, 5:60–62. Thus, only Defendants’ construction attempts to include all the forms of treatment listed in the specification.

c. Gilead Improperly Attempts to Backdoor in Plain and Ordinary Meaning

Gilead newly argues the purported plain and ordinary meaning of “treating an HIV infection” in its reply brief, which is improper. *See* D. Del. L.R. 7.1.3(c)(2) (admonishing parties not to “reserve material for the reply brief which should have been included in a full and fair opening brief.”); *compare with supra* at 40 (“What constitutes treatment for HIV is well understood in the art. In fact, it is undisputed.”); *id.* at 11. (“The claim should be construed in accordance with a POSA’s understanding of what constitutes ‘treating an HIV infection.’”). This argument is also at odds with Gilead’s choice to not advance a construction of “plain and ordinary meaning” in the first place, and is unsupported.

d. Gilead Flip-Flops on What Is Included in the Definition of Treatment

Further, Gilead’s arguments about what a POSA would purportedly understand directly contradict its argument that some “clinical outcomes” (e.g., prevention) should be excluded from the definition of “treatment.” *Compare supra* at 43, n.17 (“While [prevention] is discussed in connection with clinical outcomes, it does not bear on the construction of these claims....”); *with id.* at 11 (“A POSA would know how to evaluate whether the administered treatment “prevent[ed] the appearance of symptoms” of HIV or “prevent[ed] perinatal transmission of HIV from mother to baby.”); *also supra* at 41, n.13 (citing CDC, *HIV Treatment as Prevention*, <https://www.cdc.gov/hiv/risk/art/index.html>).

There also seems to be no space in Gilead’s definition for other embodiments such as maintaining or suppressing viral loads, preventing the onset of symptoms, and the like. Gilead implies with vague, conclusory statements that most of the embodiments listed in the patent would be included under its construction, yet there is no explanation of how to add back in these multiple embodiments, nor any real explanation of why they were excised in the first place.

Conversely, Defendants’ the clause “which does not require any particular level of efficacy or any particular level of therapeutic results,” although not a direct quote from the specification, accounts for these ignored treatment forms and outcomes. Indeed, Defendants’ construction is the only one that considers the entire specification.

**C. “a multilayer tablet”
(’846 patent: claim 1)**

Gilead’s Proposed Construction	Defendants’ Proposed Construction
Preamble is limiting. “a tablet with two or more layers, in which at least one of the claimed components is in a separate layer, wherein a layer is a section or compartment of components.”	Preamble is limiting. “at least a bilayer tablet in which at least one of the claimed components is in one of the separate layers of the at least a bilayer tablet”

1. Plaintiff’s Opening Position

Claim 1 of the ’846 patent is directed to “a multilayer tablet” comprising certain components in specific dosages. The prefix “multi-” means more than one. Therefore, the plain and ordinary meaning of a multilayer tablet is easily understood to be a tablet with two or more layers. Similarly, it is clear (and the parties agree) that the layers in question are designed to separate components—both parties agree that at least one of the claimed components is in a separate layer. The specification also makes clear what constitutes a “layer” in these tablets: a “section or compartment” of the tablet which contains specified “components.” ’846 patent at 12:15–18. The patent is explicit that there is no required orientation of the layers in a “multilayer tablet.” Ex. 11, ’846 patent at 12:12–36. These are precisely the concepts reflected in Plaintiff’s proposed construction of “a multilayer tablet”: “a tablet with two or more layers, in which at least one of the claimed components is in a separate layer.” The second portion of Plaintiff’s construction recites the specification’s explanation of what a “layer” is: “a layer is a section or compartment of components” within the tablet.

By contrast, Defendants’ proposed construction seeks to artificially narrow the scope of the claim by importing a limitation from the specification in the form of a specific embodiment: the “bilayer tablet.” But the claim is for a multilayer tablet, not a bilayer tablet. Defendants’ proposed construction does not provide any explanation of what defines a “bilayer tablet,” but instead appear to import the characteristics of certain “bilayer” embodiments in the specification. Moreover, the patent does not define the term “multilayer” by reference to the term “bilayer.” In fact, the patent never uses these terms in the same sentence, or even the same paragraph. The patent uses the descriptor “bilayer” in reference to certain embodiments, but also does not define that term—it thus remains unclear what specific characteristics of the “bilayer” embodiments Defendants seek to import into the claim through use of the term “bilayer” in Defendants’ proposed claim construction. Most importantly, no matter the precise definition of “bilayer,” the specification makes clear that layers of the claimed “multilayer tablet” are not limited to the specific stripe-like order and organization of components that Defendants’ “at least a bilayer” construction would require. The Court should reject Defendants’ proposed construction and adopt Gilead’s.

a. Gilead’s Proposed Construction Is Supported by the Specification

The Court should adopt Gilead’s proposed construction because it is lifted from—and supported by—the ’846 patent’s specification. The parties are construing the term “a multilayer tablet,” but both agree that “multilayer” is the term that drives the construction. A tablet is a recognized type of dosage form. But there are multiple forms that a tablet could take.

Consistent with the common understanding of “multi-,” the patent is explicit that there can be many layers in a multilayer tablet. The patent describes that there can be a “‘first layer’, ‘second layer’, ‘third layer’ and so forth.” Ex. 11, ’846 patent at 12:12-13; *see also id.* at col. 32. Thus,

here, “multilayer” simply means more than one layer. This is consistent with the plain and ordinary meaning of the prefix “multi-”; Merriam Webster defines it as “many, multiple, much.” Ex. 10, *multi-*, MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/multi-> (accessed Aug. 27, 2024). The patent’s usage and the general understanding are in agreement—“multi-” means more than one.

The specification is similarly clear on what a “layer” is. A layer is a “section or compartment” that contains specific components. Ex. 11, ’846 patent at 12:12-18. The point of a layer is to “distinguish the sections of the composition from each other.” *Id.* The specification demarcates what it means to be a layer (a section or compartment), what is in a layer (a component of the tablet), and the purpose of the layer (distinguishing the sections of the composition from each other). Then, too, the patent describes the orientation—or lack thereof—of the layers. For example, the specification states that, “[u]nless otherwise specified, the terms ‘first layer’, ‘second layer’, ‘third layer’ and so forth *do not specify a particular order or orientation* of the multilayer tablet formulations disclosed herein. Rather, these terms are *used to distinguish the sections of the composition* from each other and to specify the characteristics or components of each section or compartment.” Ex. 11, ’846 Patent at 12:12–18 (emphasis added).

The specification also discusses a number of different assemblies and orientations that can be a “multilayer tablet.” The ’846 patent explains that “[i]n certain embodiments, the multilayer tablet further comprises additional layers. In certain embodiments, the additional layer or layers are located between the first and second layers.” Ex. 11, ’846 patent at 32:54–57. The specification further explains that “[i]n certain embodiments, the additional layer or layers are located *on either side* of the first and/or second layer, such that they are an outside layer of the table [sic] and/or are disposed *between* the first and/or second layer and a coating layer. In some embodiments, the

additional layer or layers *encapsulate* the first and second layers.” Ex. 11, ’846 patent at 32:57–62 (emphasis added).

Finally, the term “multilayer tablet” also does not limit the manner in which the layers are made and put together into a tablet. “The first layer may be synthesized first or may be synthesized second. The first layer may be on the bottom or may be on the top or may be on a side. The term ‘first layer’ is expressly not limiting as to order and orientation.” Ex. 11, ’846 Patent at 12:33–36.

In other words, “sections of the composition” with distinctive “characteristics or components,” however oriented or ordered, whether on the top, bottom, side, or in-between, are all “layers” within the meaning of claim 1 of the ’846 patent. And as a result, the claim term “multilayer tablet” describes a tablet with “two or more layers,” *i.e.* more than one “section or compartment of components,” “in which at least one of the claimed components is in a separate layer.” This is Gilead’s proposed construction—a construction that is consistent with the patent’s use of the word multilayer.

b. Defendants Seek to Read in Limitations From an Embodiment in the Specification Through the Word “Bilayer”

The Defendants’ construction, however, is at odds with the patent’s description of a multilayer tablet. The parties’ dispute regarding the construction of this claim term turns on Defendants’ inclusion of the word “bilayer” in their proposed construction. In discussions to understand Defendants’ construction and the specific dispute over this claim term, Defendants explained that “[a] ‘bilayer tablet’ is a term of art, and was used multiple times by Gilead in the intrinsic record.” See Ex. 12, Email from C. Sorenson to R. Horwitz (Aug. 21, 2024). This confirms that Defendants’ proposed construction’s use of “bilayer” is a transparent and improper attempt to import as a claim limitation a particular characteristic of some exemplary embodiments. The specific bilayer embodiment described in the specification is a two-layer tablet in which the first

and second layers are ordered and oriented in a horizontal, “striped” fashion. See ’846 patent at 58:10–60 (Tablet F2 of Example 2). Defendants’ reliance on the term “bilayer” in their proposed construction appears to use this specific embodiment of a bilayer tablet to narrow the construction of multilayer to require the specific order and orientation of layers present in this embodiment.

This is plainly contrary to the black letter law of claim construction. Claims are read “in view of the specification,” but the Court should not “read limitations from the embodiments in the specification into the claims.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (citing *Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004)). It is improper to read limitations from an embodiment, even a preferred embodiment or the only embodiment, into the claims. *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). Defendants’ insertion of the word “bilayer” into the claim construction is a transparent attempt to improperly read in claim limitations from embodiments. On this basis alone, Defendant’s proposed construction should be rejected.

But the Defendants’ restrictive use of the word “bilayer” also fails to account for the myriad types of tablets that are explicitly covered by the plain language of the specification. For example, the patent describes a multilayer tablet as one that could have an “additional layer or layers encapsulate the first and second layer.” Ex. 11, ’846 patent at 34:54–62. The Defendants’ construction—given that it is written to restrict the type of multilayer tablets to a specific manufacturing approach—would not capture this tablet that is expressly contemplated by the specification. Similarly, Defendants’ construction would not capture the tablet configuration expressly contemplated by the specification in which “[t]he first layer” is “on a side,” and one or more additional layers are on the other side. Ex. 11, ’846 patent at 12:34–35. Defendants’ proposed construction would also limit the term “multilayer tablet” to the stripe-like order and organization

of layers disclosed in certain embodiments, which is achieved in those embodiments by compressing one layer of the tablet, and then compressing a second layer on top of it to adhere the layers. This restriction cannot be squared with the specification's disclosure that "[t]he first layer may be synthesized first or may be synthesized second. The first layer may be on the bottom or may be on the top or may be on a side." Ex. 11, '846 patent at 12:33–36. In short, the restrictions on claim scope that are imposed by Defendants' use of the word "bilayer" are contrary to the specification, and Defendants' proposed construction should be rejected.

2. Defendants' Answering Position

The crux of the dispute over this term centers upon the meaning, to a person of ordinary skill, of the root word "layer" within the term "multilayer." There is no dispute that the prefix "multi" means more than one. The ordinary meaning of "layer" is "one thickness, course or fold laid or lying over or under another," which comports with how persons of ordinary skill understood "layer" in the context of "multilayer" tablets during the relevant time period. Ex. 13, Muzzio Decl., ¶¶ 67–70, Ex. J (*Layer*, MERRIAM WEBSTER'S DICTIONARY (1994)) at 660. The specification does not express a clear intent by the inventors to redefine this term through lexicography, but it does (repeatedly) describe and rely upon a "bilayer tablet" and the assembly of such tablets to inform the intent of "layer" and the claimed "multilayer tablet." The tablet claimed may have multiple layers, but must at least be bilayer tablet, with one of the claimed components in one of the separate layers of a bilayer tablet type configuration. Moreover, one thing is abundantly clear: a "multilayer tablet" is not a monolayer tablet.

The intrinsic record practically compels Defendant's construction. As explained below, the specification (repeatedly and without deviation) employs the term of art "bilayer tablet" to disclose, describe, illustrate and/or illuminate what the patentee meant by its claim to "a multilayer tablet." The claimed tablet is "at least a bilayer tablet in which at least one of the claimed

components is in one of the separate layers of the at least a bilayer tablet.” As Dr. explains, a “bilayer tablet” is understood by a person of ordinary skill to be a tablet constructed using continuous masses that segregate incompatible active ingredients through layering, i.e., a tablet with one thickness, course or fold laid or lying over or under another. Ex. 13, Muzzio Decl., ¶¶ 30, 33, 56, 68.

The intrinsic record provides no basis to believe the patentee employed “*clear lexicography*” so as to alter the plain meaning of a “layer” to be a “a section or compartment of components” within the tablet. *Thorner v. Sony Computer Entertainment America LLC*, 669 F.3d 1362, 1366–67 (Fed. Cir. 2012) (emphasis in original). The indefinite article “a” opens the claim to include (under Gilead’s construction) a layer made from any number of “sections,” or “compartments of components” that need not be connected into a single continuous mass in the tablet. The plain meaning of “layer” is not consistent with a collection of disconnected individual “section[s] or compartment[s] of components,” since a layer is “one thickness, course or fold laid or lying over or under another,” and therefore a continuous mass. See Ex. 13, Muzzio Decl., ¶ 70, Ex. J (*Layer*, MERRIAM WEBSTER’S DICTIONARY (1994)) at 660.

As applied to tablet formulation techniques, a “layer” must be at least a continuous mass (“one thickness course or fold”) lying over another continuous mass and containing at least one of the “claimed components.” See Ex. 13, Muzzio Decl., ¶¶ 31–32, 65–66, 70. Segregation of one active ingredient in the claimed tablet using non-continuous “sections” or “compartment[s] of components” do not fall within the scope of the claimed “multilayer tablet” according to its plain and ordinary meaning. They are also not described in the specification as within the scope of “multilayered tablets,” or described and enabled with any precision at all. Gilead’s construction seeks to expand the plain meaning of the ’846 Patent claims to cover “monolayer” tablets

containing separate granules mixed into a common powder blend as a means to segregate tablet components. But monolayer tablets are not multilayer tablets and are clearly distinguished as such in the specification. Ex. 13, Muzzio Decl., Ex. B ('846 Patent), 9:54–59 (“In particular, dissolution of Formula I [(bictegravir) varies depending on whether . . . the tablet is a monolayer or a multilayer tablet.”).

The specification also makes clear that “powder blends” made using granules (or otherwise) are not layers themselves, but that single powder blends can be formed into single layers, while other single powder blends can be formed into other single layers to provide bilayer (trilayer, etc.) tablets. Ex. 13, Muzzio Decl., Ex. B ('846 Patent), 58:10–60 (bilayer tablet prepared from “final powder blend” with emtricitabine/TAF granules and an extragranular lubricant compressed into *layer 1* and “final powder blend” with BIC granules and extragranular filler and lubricant compressed into *layer 2*).

Powder blends containing separate granules of different composition and extragranular excipients are not “layers.” See also Ex. 13, Muzzio Decl., ¶ 42. Once compressed (or otherwise shaped), a final powder blend can be made into a single layer, which is a monolayer tablet, assuming it is not subsequently combined with another powder blend which is then made into a separate layer. Monolayer tablets containing granules, e.g., different granules, are not covered by the '846 Patent claims.

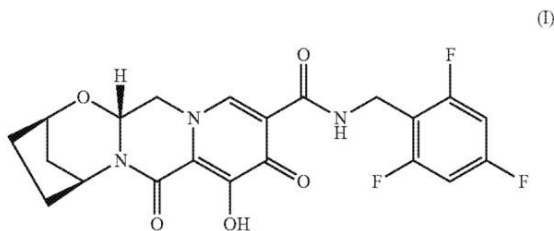
Finally, Defendants’ construction does not (as Gilead contends) seek to limit the scope of this claim to a single embodiment. With “at least a bilayer tablet,” the claim has its full scope, allowing for additional layers above, below, or on either side of the bilayer tablet, as well as in between, or even encapsulating, the core bilayer aspect of the claimed tablet. It includes tablets with three (tri-layer), four (quad-layer), or more layers. The use of “bilayer tablet” is simply to

emphasize that the claimed layers are in fact continuous masses (one layer is a thickness, course or fold laid on another thickness, course, or fold) within the tablet.

a. The Intrinsic Evidence Emphasizes Segregating Active Ingredients Through Layering

Claims. There are many aspects of the interpretation of the claim language to which the parties agree. The full text of Claim 1 in context is helpful, as follows:

1. A multilayer 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 wherein the tablet has a total weight of less than about 1000 mg.

Ex. 13, Muzzio Decl., Ex. B ('846 Patent), 76:34–52 (claim 1). The parties agree that the preamble of the claim, “a multilayer tablet,” is limiting, and that the “multilayer tablet” has specific amounts of three different active ingredients: 25 mg of tenofovir alafenamide (TAF), 200 mg of emtricitabine (FTC), and 50 mg of “the compound of Formula I” which is bictegravir (BIC). The parties agree to identify each of the amounts of the three active ingredients as “claimed components” in each of their respective constructions. Although Gilead argues otherwise, the parties also agree that the claimed tablet may have more than one “layer.”

Specification. The patent specification “is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term.” *Vitronics*, 90 F.3d at 1582. It is possible for a specification to reveal a special definition that differs from the plain

meaning a word in a claim, but to do so a patentee must “clearly express an intent” to so define the term at issue. *Thorner*, 669 F.3d at 1365 (quoting *Helmsderfer v. Bobrick Washroom Equip., Inc.* 527 F.3d 1379, 1381 (Fed. Cir. 2008)).

Although Gilead contends otherwise, the specification of the ’846 Patent does not, with clear lexicography, alter the plain meaning of the root word “layer.” The ’846 Patent specification describes multiple different theoretical types of solid oral dosage forms, but those containing all three active ingredients (BIC, TAF, and FTC) use layering as the means for segregating the active ingredients. Ex. 13, Muzzio Decl., Ex. B (’846 Patent), 1:63–53:36. And, as the patent (repeatedly) discloses, one layer is, e.g., “substantially free of [TAF], and/or the second layer is substantially free of [BIC].” See, e.g., Ex. 13, Muzzio Decl., Ex. B (’846 Patent), 10:10–15; 10:24–37; 10:58–11:20.

In a section describing general “methods for producing the compositions and dosage forms (in particular tablets) disclosed herein,” the patentee describes compression of one active ingredient “as a first layer” and then compressing the other two actives into a tablet “as a second layer.” *Id.* at 53:36–54:28.¹⁹ The same section also notes that tablets can be made by “compression or molding.” *Id.* at 54:24.

After the various embodiments of tablets are listed, the patentee disclosed the specific way in which two “Bilayer Tablets” allegedly demonstrated enhanced dissolution and bioavailability of the BIC ingredient in later experiments (tablets “F2” and “F7”). *Id.* at 58:43–60. The patentee prepared one dry granulation of a “final powder blend” containing inactive ingredients combined

¹⁹ As is also explained in the accompanying declaration of Dr. Muzzio, the specification incorporates by reference a well-known textbook that (in more detail) explains how formulators granulate active ingredients to make powder blends, including the construction of multilayer tablets. Ex. 13, Muzzio Decl, ¶¶ 55–56.

with TAF and FTC. *Id.* at 58:44–50. Separately, another “final powder blend” with BIC and additional inactive ingredients was prepared. *Id.* at 58:50–56. The entire content of the first “final powder blend” was then “compressed as layer 1,” and the entire content of the second blend was then “compressed as layer 2 to give a final bilayer tablet core.” *Id.* Though a “final powder blend” may be formed into “one layer,” it is not a “layer” itself and cannot contain multiple layers within it. Instead, the specification makes clear that one “final powder blend” provides for one “layer” and that more than one “final powder blend” can individually be formed into multiple “layers,” e.g., after compression or molding. *See also id.* at 66:55–67:62.

As Dr. Muzzio explains, using a bilayer compression process as an example, each of the two layers are made into separate continuous masses (each a thickness, course or fold laid over another) in a layered manner. *See Ex. 13, Muzzio Decl., ¶ 32.* The patentee also disclosed a flow diagram that illustrates the preparation of such a tablet, and the final process step is described as a “Bilayer Compression.” *Ex. 13, Muzzio Decl., Ex. B (’846 Patent), Fig. 6.* Dr. Muzzio explains that this “bilayer compression,” is a process that creates a continuous mass for each different “final powder blend” formed into a multilayered tablet. *See Ex. 13, Muzzio Decl., ¶ 42.*

The specification, in a section describing several “particular embodiments,” describes various iterations of tablets, all of which segregate BIC from TAF and FTC by use of layers. *Ex. 13, Muzzio Decl., Ex. B (’846 Patent), 9:63–12:11.* After listing various iterations of the content of various ingredients of first or second layers of the “particular embodiments,” the specification explains that “the terms ‘first layer’, ‘second layer’, ‘third layer’ and so forth do not specify a particular order or orientation of the multilayer tablet formulations disclosed herein.” *Ex. 13, Muzzio Decl., Ex. B (’846 Patent), 12:12–15.* Importantly, the same paragraph clarifies that the terms “first layer,” “second layer” and so forth “are used to distinguish *the sections of the*

composition from each other and to specify *the characteristics or components of each section or compartment.*” *Id.* at 12:15–18 (emphasis added). This passage emphasizes sequentially numbered layers are meant to distinguish different “sections of the composition,” not to redefine what a “layer” means. The “orientation” of single layers in that tablet, e.g., top/bottom or side- to- side, is just a matter of perspective, e.g., rotating tablets 90 degrees, and does not conflict with the plain meaning of “layer” itself. *See also* Ex. 13, Muzzio Decl., ¶ 40. This passage is not (as Gilead suggests) a clear intentional effort by the patentee to redefine the plain meaning of “layer” to cover multiple unconnected granules as “a section or compartment of components,” e.g., in a monolayer tablet.

Later in the specification, the patentee reiterates the same concept of what it means by use of the terms “first layer” and “second layer.” Ex. 13, Muzzio Decl., Ex. B (’846 Patent), 32:49–53. Here, the patentee explains that the use of those terms in describing “the multilayer tablets disclosed herein,” are “not intended to indicate the method by which the tablets are produced, in particular the order in which the layers are obtained.” *Id.* The same section continues, emphasizing that additional layers in the multilayer tablet could be located “between the first and second layers,” and “on either side of the first and/or second layer,” and that the additional layer(s) could even “encapsulate the first and second layers.” *Id.* at 32:44–62; *but see also id.* at 77:6–78:3 (distinguishing a “film coating” from the term “layer” in claim 9, 47:11–49:29 (distinguish the same); *see also* Ex. 13, Muzzio Decl., ¶ 41. Again, this section does not redefine to a person of ordinary skill what a “layer” in a multilayer tablet means. This passage is explaining that each layer can be located on the top, bottom, or side of another layer, with additional layers laid on the top, bottom, or side of “the first and second layer,” or even encapsulating “the first and second

layer” of the tablet. If additional layers were included, the tablet would contain more than a “the first and second layer” and be considered a tri-layer, quad-layer tablet, and so on.

Also, among the examples of tablets disclosed in the ’846 Patent specification that were made (and tested) by the patentee, only “Bilayer tablet F2” and “Bilayer tablet F7” allegedly demonstrated (in the disclosed experiments) enhanced dissolution and pharmacokinetic properties. The “Bilayer tablet F2,” and “Bilayer tablet F7,” are both tablets that segregate BIC in its own layer, away from the other two active ingredients in another layer, and both layers were made with “bilayer compression.” Ex. 13, Muzzio Decl., Ex. B (’846 Patent), Figs. 1–4, and 61:1–6 (alleging 30% higher exposure of one active ingredient from the “bilayer tablet formulation F2,” as compared to single agent tablets), 66:50–53 (alleging “the 50 mg bilayer formulation (tablet F7) exhibited enhanced dissolution . . .”), 69:30–41 (F7 with similar pharmacokinetic exposure as that found in tablet F2)); *see also* Ex. 13, Muzzio Decl., ¶ 42. Clearly, segregation of the active ingredients by means of layering, according to the plain meaning of “layer” is an important aspect of the claimed invention. The law is clear that the construction of a claim term may include limitations discussed in a specification where the patentee describes a particular feature as “important” to the invention. *Sentry Prof. Prods. v. Eagle Mfg. Co.*, 400 F.3d 910, 915 (Fed. Cir. 2005); *see also Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350, 1354–55 (Fed. Cir. 2006). Accordingly, defining the claimed “a multilayer tablet” to include “at least a bilayer tablet” is consistent with the specification.

Dr. Muzzio also provides examples from three other patent publications disclosed by the patentee and reviewed by the examiner, all of which also employ the term “bilayer tablet” to explain the manner in which active ingredients in multilayered tablets are segregated. *See* Ex. 13, Muzzio Decl., Exs. D–F; *see also id.* ¶¶ 46–54. One such publication has a granulation of TAF

and FTC, which is also formed using bilayer compression into one layer in a tablet. *See* Ex. 13, Muzzio Decl, Ex. F (WO '720), ¶¶ [0342, 0344, 0349] (“Treatment E” described as having 25 mg of TAF and 200 mg FTC, which was “prepared as bilayer tablets what were manufactured by compression of the elvitegravir/cobicistat layer and [FTC]/[TAF] layer, tablet film-coating, and packaging.”). This “bilayer” tablet stands in contrast in that publication to another disclosed monolayer tablet, where two separate granulations are mixed to provide a single powder blend before being compressed into a single layered tablet. *Id.* at ¶ [0342] (describing a monolayer tablet “prepared by blending of [FTD and TAF] granulation with elvitegravir granulation and cobicistat, tablet compression, tablet film-coating, and packaging.”) As Dr. Muzzio explains, all such references confirm that persons of ordinary skill understand that a “bilayer tablet” is a term of art, meant to emphasize segregation by arranging active ingredients in layers that are continuous masses. Ex. 13, Muzzio Decl., ¶¶ 48, 50–51, 53. A “multilayer tablet” allows for two, three, four, or so on of the continuous masses within the multilayer tablets. Ex. 13, Muzzio Decl., ¶ 32.

Prosecution. The prosecution of the '846 Patent, which Gilead ignores, also establishes that the patentee (to secure issuance of the claims) emphasized the importance of a “bilayer tablet” configuration to convince the examiner that the alleged unexpected results of such a tablet design supported the issuance of the claims.

During prosecution, after broader claims were repeatedly rejected based on the prior art, the patentee amended claim 1 by adding “multilayer” to the preamble in an amendment filed on September 10, 2018. Ex. 13, Muzzio Decl., ¶ 60, Ex C at BICANDA00006420, 6422–25. In its accompanying arguments, the patentee states that the “instantly claimed formulation has surprising pharmacokinetic benefits,” and noted that “a bilayer tablet formulation of [BIC, TAF,

and FTC] results in approximately 30% higher total exposure of [BIC] compared to the corresponding total exposure achieved with a single agent formulation of [BIC] co-administered with a fixed dose combination of [TAF and FTC].” Ex. 13, Muzzio Decl., ¶ 60, Ex C at BICANDA00006424–25 (emphasis added).

The examiner nonetheless rejected the amended claims in another office action dated December 21, 2018. See Ex. 13, Muzzio Decl., ¶ 62, Ex. C at BICANDA00006439. The patentee again responded, emphasizing that “Formulation F2,” a bilayer tablet, resulted in “approximately 30% higher exposure of bictegravir,” as compared to the same dosage amounts given in separate tablets. *Id.* at ¶ 63, Ex. C at BICANDA00006457. In a subsequent notice of allowance, the examiner was convinced, and stated the patentees “have shown a 30% higher exposure of bictegravir in a fixed dose combination of [BIC, FTC, and TAF] relative to its exposure when co-administered as a single agent of [BIC] with a fixed dose combination of [FTC and TAF].” *Id.* at ¶ 58, Ex. C at BICANDA00006507. Thus, the bilayer tablet configuration, which segregates ingredients into their own layers as separate continuous masses, was the primary reason for the examiner’s decision to allow the claims.

b. The Extrinsic Evidence

It is well established that while interpreting words used by patent claims, a district court should first look to the language of the claim itself to understand how that language is understood by those skilled in the art. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*) (“The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation.”) And, in addition to the other intrinsic evidence available, to understand how a person of ordinary skill in the art would understand a claim term, the Federal Circuit has expressly held that district courts may rely on expert testimony. See *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1370–

71 (Fed. Cir. 2017) (deferring to the district court’s underlying determination, based on expert testimony, on what a person of ordinary skill would understand “vitamin B12” to mean).

To this end, Defendants submit herewith the declaration of Dr. Muzzio, a noted expert in the fields of tablet formulation. Ex. 13, Muzzio Decl, ¶¶ 5–17, Ex. A. Dr. Muzzio provides a background explanation as to what granulations of tablet ingredients entails, and what a “bilayer tablet” means to the person of ordinary skill in the art. Ex. 13, Muzzio Decl, ¶¶ 26–34. And, according to Dr. Muzzio, a skilled artisan understands that a “bilayer tablet,” is one typically made by compressing one final granulation powder blend into one “layer” to form one continuous mass of the material, and the compression of other final granulation powder blends in another layer as a separate continuous mass of material. *Id.* at ¶ 32. Dr. Muzzio’s testimony is supported by other texts that he has located as well, as set forth in his declaration. *Id.* at Exs. D–K.

c. Defendants’ Construction Is Consistent With the Intrinsic Record

The parties are in accord that the proper construction of “the multilayer tablet” requires a careful study, and understanding of, the disclosure provided in the specification of the patent. As Gilead states, its construction “*is lifted from—and supported by—the ’846 Patent’s specification.*” *Supra* at 49 (emphasis added). Defendants’ construction also relies upon, and employs, concepts and words described in the patent’s specification, as well as its prosecution history. The entire intrinsic record illuminates what the patentee intended to claim as “a multilayer tablet,” which is not a tablet that segregates active ingredients by use of discontinuous “sections or compartment[s] of components” scattered about a tablet, e.g., a monolayer tablet, in ways different from the plain meaning of “layer”.

The use of the term “bilayer tablet” in Defendants’ construction makes sense, as the patentee’s explicit disclosure of layered tablets as one type of segregation, necessarily illustrates

what the patentee meant by “a multilayer tablet.” It is “at least a bilayer tablet,” which segregates at least one of its claimed components into “one of the separate layers of the at least a bilayer tablet.” Employing the term of art of a “*at least* a bilayer tablet” in the construction ensures the claim is construed to capture no more, and no less, than what the patentee disclosed as its invention.

d. Gilead’s Construction Cannot Be Correct

Gilead’s construction would in effect expand the claim to include tablets that segregate components within a monolayer tablet, in separate granulations or otherwise. But monolayer tablets clearly are not multilayer tablets, and multilayer tablets are only one way to “segregate” components as provided by the specification. E x . 13, Muzzio Decl., Ex. B (’846 Patent), 3:34–51, 55:53–61. Although segregation of one claimed component from another is possible using alternative tablet configurations, those alternatives are not specifically described in the specification, and those alternative segregation methods necessarily include tablets that are not “multilayer,” e.g., monolayer tablets containing separate granules of claimed components. *See also* E x . 13, Muzzio Decl., ¶ 44–45.

This patentee described segregation of active ingredients in “a multilayer tablet” using language based on a bilayer tablet, which allows for expansion into a tri-layer, quad-layer tablet, etc. But the ’846 cannot possibly include segregation of claimed components within a single layer of a monolayer tablet. Such an interpretation would turn the express claim language on its head. Ultimately, only tablets constructed in a bilayer type configuration achieved the allegedly surprising dissolution and pharmacokinetic properties that convinced the Patent Office to allow these claims. The proper construction cannot be one that expands the claim scope to include such a broad, undisclosed, and unsupported manner as the Gilead proposes here.

e. The Defendants’ Construction Is Not Limited to One Embodiment

Gilead’s Opening Brief also employs a *straw man* fallacy. Gilead attacks an argument that the Defendants have not made. Defendants’ construction is that the claimed “multilayer tablet” is properly construed to mean “*at least* a bilayer tablet, . . .” Defendants do not contend the claimed tablet is limited to *only* a bilayer tablet. By “at least” there can be more than two layers, and the orientation of those layers is simply a matter of perspective.

3. Plaintiff’s Reply Position

Defendants propose that a “layer” is “one thickness, course or fold laid or lying over or under another.” *See supra* at 52. Their full construction is set forth below:

PLAINTIFF’S PROPOSED CONSTRUCTION	DEFENDANTS’ PROPOSED CONSTRUCTION
Preamble is limiting. “a tablet with two or more layers, in which at least one of the claimed components is in a separate layer, wherein a layer is a section or compartment of components.”	Preamble is limiting. “at least a bilayer tablet in which at least one of the claimed components is in one of the separate layers of the at least a bilayer tablet, wherein a ‘layer’ is ‘one thickness, course or fold laid or lying over or under another.’”

Defendants’ proposed construction selects a single type of embodiment (bilayer) to define “multilayer” and imports an extrinsic lay dictionary definition for the construction of “layer.” But it is improper to introduce an exemplary embodiment—bilayer—into the claims. And it is the patent, not Defendants’ dictionary, that explains the plain and ordinary meaning of the term “layer.” Defendants argue that their definition of a “layer” is the correct plain and ordinary meaning, and that Gilead’s proposed construction is an attempt to alter that plain and ordinary meaning. But this core premise of Defendants’ argument is wrong—it assumes that a lay dictionary from 1994 supplies the correct, singular, and authoritative plain and ordinary meaning of the term

“layer” that trumps the patent’s definition. Contrary to Defendants’ argument, Gilead does not assert that the patentee altered the meaning of “layer” through lexicography. Gilead relies on the specification of the patent as confirmation of the plain and ordinary meaning, which is consistent with Gilead’s proposed construction.

a. Defendants Transparently Seek to Import Limitations From Embodiments Through the Term “Bilayer”

The parties agree that the prefix “multi-” means “more than one” (i.e. “two or more”). See *supra* at 53. The natural inference from this meaning is that “a multilayer tablet” means “a tablet with two or more layers.” Defendants instead argue that “a multilayer tablet” means “at least a bilayer tablet,” improperly importing the meaning of a separate term of art and exemplary embodiment (“bilayer”) into the claim construction dispute. The reason for this switch is clear—Defendants seek to import characteristics of “bilayer” embodiments as claim limitations.

It is improper to read limitations from an embodiment, even a preferred embodiment or the only embodiment, into the claims. *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). But in their answering brief, Defendants essentially acknowledge that this is what they are advocating. For example, Defendants assert that “the specification (repeatedly and without deviation) employs the term of art ‘bilayer tablet’ to disclose, describe, illustrate and/or illuminate what the patentee meant by its claim to ‘a multilayer tablet.’” *Supra* at 53. Defendants further refer to “the *core bilayer aspect* of the claimed tablet.” *Id.* at 55 (emphasis added). Needless to say, for claims in which the term “bilayer” does not appear (including every claim of the ’846 patent), there is no such thing as “the core bilayer aspect of the claimed tablet.” Defendants are correct that “segregation of the active ingredients by means of layering, according to the plain meaning of ‘layer’ is an important aspect of the claimed invention.” *Id.* at 59. But Defendants’ proposed construction would require segregation of the active ingredients by means of *a bilayer tablet*, i.e.

by way of a particular manufacturing approach resulting in a particular order and orientation of layers, neither of which are required by the claim itself. That is wrong, and Defendants' transparent attempt to import claim limitations from embodiments should be rejected.

In its opening brief, Gilead discussed in detail the specific characteristics of embodiments that Defendants are seeking to incorporate as claim limitations through the term "bilayer." See *generally supra* at 51-52. These are characteristics of *particular embodiments* of the claimed "multilayer tablet," which are neither required nor supported as limitations. To be sure, Defendants' proposed "at least a bilayer tablet" is a *species* of the claimed "multilayer tablet." Limiting the claim scope to Defendants' proposed construction would require importing these characteristics of "bilayer" embodiments as claim limitations.

Further, the patent specification makes clear that bilayer is more restrictive than "multilayer." "Multilayer" appears in the patent 128 times; "bilayer" appears separately only 44 times. More importantly, after a single appearance in the patent's figures, the term "bilayer" doesn't appear until column 49, in descriptions of *specific embodiments*. Multilayer is used starting at column 3 and throughout the patent, as a description of the broader invention in the summary and detailed description of the patent, in addition to the specific embodiments.

Defendants also mischaracterize the prosecution history in support of this argument. During prosecution, the patentee demonstrated "surprising pharmacokinetic benefits" associated with administering the claimed single tablet regimen over administering two separate tablets. Ex. 13, Muzzio Decl. Ex. C at BICANDA00006424–6425. The single tablet formulation administered to demonstrate this surprising benefit was a bilayer tablet.²⁰ Defendants claim that this "*bilayer*

²⁰ Gilead's adult Biktarvy® product, under development at the time of these experiments, is a bilayer tablet. That is why this formulation was used. This fact has no bearing on the meaning of any claim term.

tablet configuration, which segregates ingredients into their own layers as separate continuous masses, *was the primary reason* for the examiner’s decision to allow the claims.” *Supra* at 61 (emphasis added). That claim is baseless. Defendants quote most of the relevant portion of the examiner’s explanation for their decision:

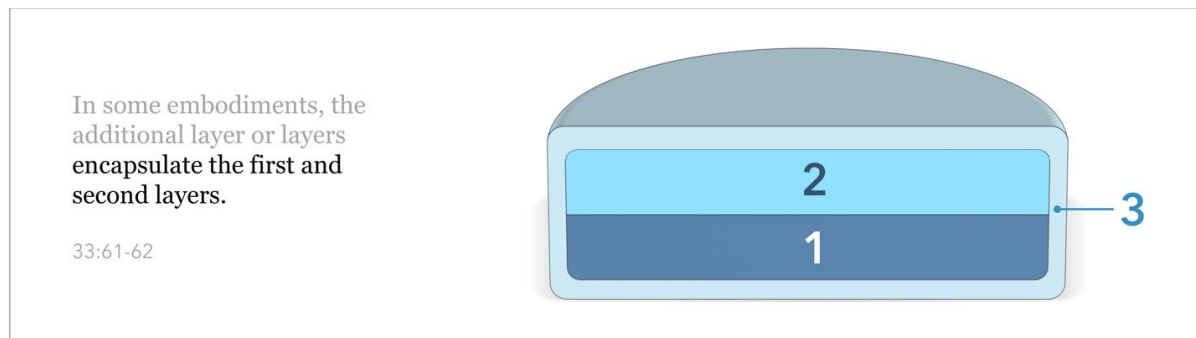
The prior art does not teach *all three drugs within the same tablet*. Applicants have shown a 30% higher exposure of bicitegravir in a *fixed dose combination* of bicitegravir, emtricitabine, and tenofovir alafenamide relative to its exposure when co-administered as a single agent of bicitegravir with a fixed dose combination of emtricitabine and tenofovir alafenamide.

Ex. 13, Muzzio Decl. Ex. C at BICANDA00006507 (emphasis added); *see id.* at 27 (quoting same). The examiner’s explanation does not include the term “layer,” never mind the term “bilayer.” The pending claims directed to “a multilayer tablet” were then allowed based on this analysis. The prosecution history does not support Defendants, and instead confirms Gilead’s position that there is no such thing as “the *core bilayer aspect* of the claimed tablet.”

b. Defendants Rely on Extrinsic Evidence to Generate a Definition of “Layers” That Is Incorrect and Unsupported

In addition to importing a limitation from the specification, Defendants assert that the plain and ordinary meaning of a “layer” comes from an extrinsic source: a lay dictionary sponsored by a paid expert. *Supra* at 52-53. Defendants utilize the declaration of an outside expert, Dr. Fernando Muzzio, to argue that “layer” means “‘one thickness, course, or fold laid or lying over or under another.’” *Id.* Dr. Muzzio generates this definition in primary reliance on a 1994 edition of Merriam-Webster’s Collegiate Dictionary. Ex. 13, Muzzio Decl. at ¶ 70. Defendants’ resulting position on the meaning of “layers,” and therefore the meaning of “multilayer,” is inconsistent with the plain and ordinary meaning, from the specification or common sense, read in light of the patent specification. And, it would exclude several embodiments disclosed in the specification as “multilayer” tablets.

Dr. Muzzio’s 1994 dictionary definition requires that a layer be over *or* under another layer. That same dictionary defines “or” as “a function word to indicate an alternative.” Ex. 14, *Or*, Merriam-Webster’s Collegiate Dictionary (10th Ed. 1994); *see also* Ex. 15, *Or*, Merriam-Webster’s Collegiate Dictionary (11th Ed. 2014). That means layer A can be laying over layer B *or* laying under layer B, but cannot be laying both over and under at the same time. This definition of a “layer” is not consistent with the intrinsic evidence. For example, the specification specifically contemplates a configuration in which “the additional layer or layers encapsulate the first and second layers” as a type of multilayer tablet. Ex. 11, ’846 patent at 32:57–62. In this configuration, visualized below, a layer (**layer 3**) can be over *and* under *and* around the first and second layers.



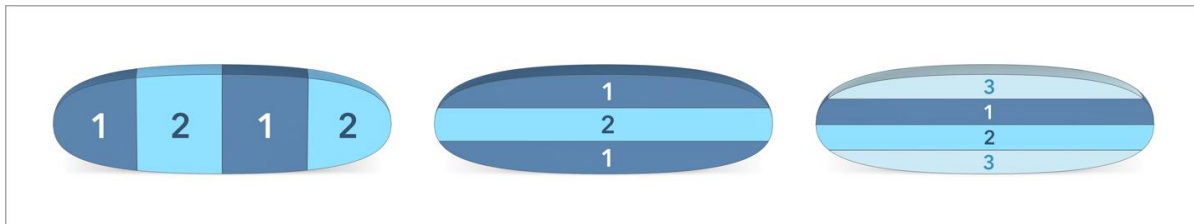
The Defendants’ requirement that a layer be “one thickness, course, or fold laid or lying over *or* under another” is inconsistent with at least this embodiment from the specification, which has the same layer over *and* under the other layers.

Defendants’ subsequent analysis does not address this problem or others like it, and instead assumes *ipse dixit* that Dr. Muzzio’s definition is correct. For example, citing Dr. Muzzio, Defendants state that “[t]he plain meaning of ‘layer’ is not consistent with a collection of disconnected individual ‘section[s] or compartment[s] of components,’ *since a layer is ‘one thickness, course or fold laid or lying over or under another,’ and therefore a continuous mass.*” *Supra* at 52-53 (emphasis added). But according to the patent, a layer is a “section or compartment”

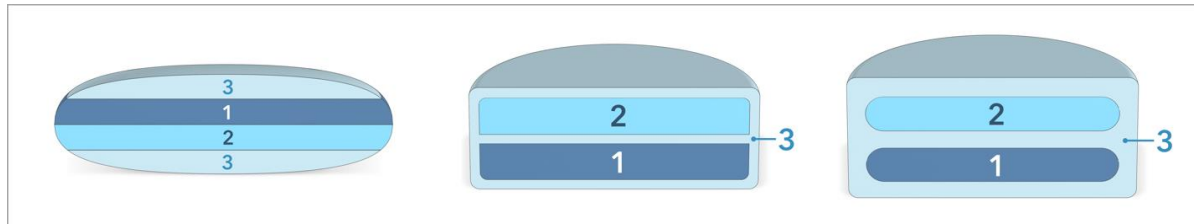
of the overall tablet that contains specific components. Ex. 11, '846 patent at 12:12–18. A layer “distinguish[es] the sections of the composition from each other,” and the term does not restrict the order of layers with respect to each other, their orientation in space, the number of layers, or whether the layers are repeated. *Id.* at 12:12–18, 12:33–36, 32:49–62.

The specification does not say that layers must be a “continuous mass.” In fact, Dr. Muzzio appears to invent the requirement of “continuous masses,” and the rejection of “multiple unconnected” masses, out of whole cloth—his declaration uses the phrase “continuous mass” 12 times, but he never cites any reference in which the phrase appears (including the patents, in which the phrase does not appear). *See* Ex. 13, Muzzio Decl. at ¶¶ 29, 32, 33, 65, 68–71.

Defendants’ requirement that “layers” be single “continuous masses” and not “multiple unconnected” masses would exclude any formulation having more than one layer with the same composition of ingredients, such as repeating layers in the configuration 1/2/1. In other words, in Defendants’ view, a “multilayer” tablet may include only one “layer” of a given composition. But there is no such restriction set forth anywhere in the patent. Defendants’ framing would thus exclude a “layer cake”-type configuration (shown below). Ex. 11, '846 patent at 32:54–62 (“[T]he multilayer tablet further comprises additional layers ... [i]n certain embodiments, *the additional layer or layers* are located on either side of the first and/or second layer, such that they are an outside layer.”). No POSA would understand the term “multilayer” to exclude these embodiments.



Acknowledging the reality that layers may repeat, may be unconnected, and need not be (as Defendants would require) a single, continuous mass for each component comprising the same ingredients, there is no reasoned way to distinguish the types of multilayer tablets below:

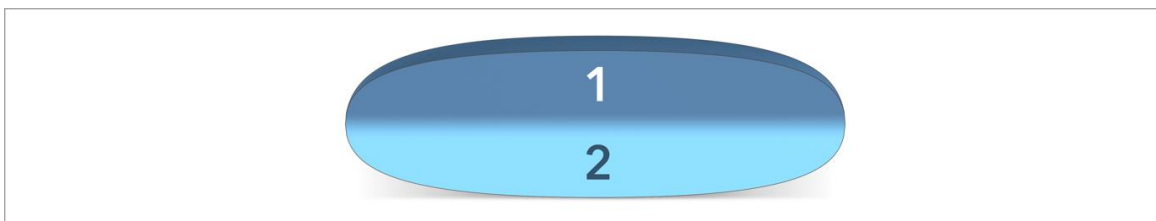


c. Gilead’s Proposed Construction Is Consistent With the Intrinsic Evidence

Gilead’s proposed construction is rooted in the principles of construing a term’s plain meaning and the patent’s intrinsic evidence. Defendants repeatedly insist that Gilead’s position is premised on an argument that the patentee “alter[ed] the plain meaning of the root word ‘layer’” “with clear lexicography.” *See, e.g., supra* at 56. Defendants are incorrect. Gilead has not argued and does not argue that the patentee altered the meaning of “layers” through lexicography, because the patentee did not do so. “To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning.” “[D]isclos[ing] a single embodiment or us[ing] a word in the same manner in all embodiments” is not enough. “The patentee must clearly express an intent to redefine the term.” *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (internal citations and quotations omitted). Defendants fail to meet this standard because the specification does not reflect any intent to “redefine the term” “multilayer” (or “layer”). The Court should thus engage in the ordinary inquiry to determine “how a person of ordinary skill in the art would understand [the] claim term ‘in the context of the entire patent, including the specification.’” *Trs. of Columbia Univ. in the City of New York v. Symantec Corp.*, 811 F.3d 1359, 1362 (Fed. Cir. 2016) (internal quotation omitted).

Gilead’s proposed construction flows from the plain and ordinary meaning of the term “layer,” which is illustrated by the specification’s discussion of the term—what a layer is and what a layer does. A layer is a “section or compartment” of the overall tablet that contains specific components. Ex. 11, ’846 patent at 12:12–18. The purpose of a layer is to “distinguish the sections of the composition from each other.” *Id.* The term “layer” does not restrict the order and orientation of layers with respect to each other. *Id.* at 12:12–18, 12:33–36, 34:49–62. The term “layer” does not restrict the number of layers. *Id.* The term “layer” does not restrict the method of synthesizing layers. *Id.* And the term “layer” is expressly broader than a bilayer. *Id.* at 32:35–48 (characterizing a bilayer tablet as “one embodiment”). Taken together, the specification’s disclosure confirms that Gilead’s proposed construction reflects the plain and ordinary meaning of the term “layer”: “a section or compartment of components.”

Despite Defendants’ arguments otherwise, the specification’s discussion of the concept of “segregation” is also consistent with Gilead’s proposed construction. Defendants are correct that “segregation of one claimed component from another is possible using alternative tablet configurations” other than layers. *Supra* at 63. For example, a tablet could be formulated with one component concentrated on one side and a second concentrated on the other side:



The components in this configuration are “segregated” because they are “physically discrete,” see Ex. 11, ’846 patent at 55:53–56, but this configuration is not “layers,” because there is no discrete “section[] of the composition” with well-defined boundaries which distinguish it from other sections based on its “characteristics or components,” *id.* at 12:12–18. The existence of

configurations comprising “segregation” but not “layers” does not support Defendants’ assertion that tablets “containing separate granules of claimed components” are necessarily “monolayer” (not “multilayer”) tablets. *See supra* at 63. Defendants simply assume this conclusion because it favors their argument.

Additionally, Defendants seem to suggest that Gilead’s argument is that “multiple unconnected granules” together constitute a *single* layer. *Supra* at 54, 58. That is incorrect. Defendants’ premise is that the “plain meaning of ‘layer’ is not consistent with a collection of disconnected individual ‘section[s].’” *Id.* at 54. But in a formulation comprising “multiple unconnected granules,” the *individual granules* are consistent with the specification’s discussion of layers as “sections or compartments of components.” Contrary to Defendants’ arguments, and as described above, nothing about this disclosure suggests that the tablet cannot include many “layers” containing a particular component, with each such layer serving to segregate that component from other portions of the tablet. For all of the reasons explained, this is entirely consistent with the plain and ordinary meaning of the term “multilayer.”

4. Defendants’ Sur-Reply Position

As the progression of briefing on this term has shown, the true dispute between the parties lies in the meaning, to a person of ordinary skill in the art, of the term “layer.” As was explained in Defendants’ Opening Brief, a “layer” should be given its ordinary meaning, which is “one thickness, course or fold laid or lying over or under another.” Defendants believe the intrinsic record confirms that the definition of the term “layer” is necessarily informed by the specific type of segregating function that layers impart to the claimed tablets. Ex. 13, Muzzio Decl, ¶¶ 35–63.²¹

²¹ Dr. Muzzio’s analysis does not blindly rest upon a single dictionary definition, or *ipse dixit* reasoning. Dr. Muzzio’s analysis includes an analysis of the entire intrinsic record (including other patents Gilead disclosed to the Patent Office with monolayer tablets), as well as several texts in the pharmaceutical

Defendants do not, however, contend the claims of '846 Patent are limited by the number of layers, how those layers are constructed, or how multiple layers might (in theory) be oriented in the tablet. Ex. 13, Muzzio Decl., Ex. B ('846 Patent), 3:34–51; *see also* Ex. 13, Muzzio Decl., ¶¶ 44–45 (analysis of the specification's definition of segregated tablets).

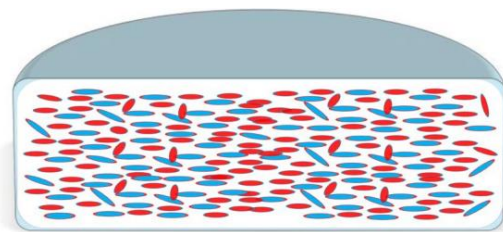
In contrast, Gilead lifts its definition of “layer” from out-of-context snippets of the specification, so that it can redefine a “layer” to mean “a section or compartment of components.” (Ex. 13, Muzzio Decl., Ex. B ('846 Patent), 12:12–18; 32:49–53.) Gilead engages in this semantic exercise because it hopes to expand its claims to capture an entirely different way of segregating active ingredients in a tablet – by “sections,” or by “compartments of components,” dispersed throughout a tablet without any semblance of layering. Indeed, by importing the words “section” or “compartments of components” into the claims, Gilead hopes to dramatically expand the literal scope of those claims – effectively removing the “multilayer” limitation entirely. (*See* Ex. 13, Muzzio Decl., ¶¶ 66–71.) This is not the claim scope the Patent Office allowed.

Gilead's Reply confirms this motive. In the last paragraph of Gilead's Reply, it admits that in a tablet with “multiple unconnected granules,” the *individual granules* are consistent with the specification's discussion of layers as “sections or compartments of components.” *Supra* at 72 (emphasis in original). Gilead proposes, with nothing but attorney argument supporting this theory, that the POSA would understand *individual granules* within a monolayer tablet to be “layers.” While this argument may be creative, it is unsupported by evidence and simply not correct.

formulation cannon, all of which emphasize that persons of ordinary skill in this art understand that a layer is a continuous mass – or “one thickness, course, or fold laid or lying over or under another.” *See* Ex. 13, Muzzio Decl., ¶¶ 35–63 (intrinsic record analysis); and ¶¶ 64–71 (POSA's understanding of “layer”).)

The intrinsic record of the '846 Patent contains no support for the notion that the '846 Patent describes, enables, or claims a tablet that segregates incompatible active ingredients using “individual granules” mixed throughout a monolayer tablet. The specification, in a section describing several “particular embodiments,” describes various iterations of tablets, all of which segregate BIC from TAF and FTC by use of layers. Ex. 13, Muzzio Decl., Ex. B ('846 Patent), 9:63– 12:11. There is no tablet disclosed that segregates BIC from TAF and FTC by use of different “individual granules” in any configuration. And even if there were, the specification provides no guidance connecting individual granules with different “layers” in a tablet. Further, the only tablets that achieved the alleged surprising results were tablets with BIC segregated into one layer, and the other active ingredients segregated into another layer. *Id.* at Fig. 6, 58:43–60; 61:1–15. Importantly, layering is understood by a POSA to be one way (among options) to keep incompatible drugs segregated from each other in the same tablet. Ex. 13, Muzzio Decl., ¶¶ 26–34.

Individual granules in a monolayer tablet are not layers in a multilayer tablet. Ex. 13, Muzzio Decl. ¶¶ 29, 71. A monolayer tablet is made by compressing granules, such as those containing different active ingredients, into a tablet as illustrated below:



Here, the red ovals represent one granulation, and the blue another (although not drawn to scale – there are likely millions of granules from each granulation mixed together in an actual monolayer tablet). See Ex. 13, Muzzio Decl., Ex. D, ¶ [0091] (providing description of a “single layer tablet” with two separate granulations); Ex. F, ¶¶ [334] (noting the monolayer tablets “were manufactured

by blending of [FTC]/[TAF] granulation with elvitegravir granulation and cobicistat, tablet compression, tablet film-coating, and packaging.”). In this tablet design, each granule is (in a sense) segregated from the other, but each is also mixed throughout the tablet before compression occurs. Detailed examples of such monolayer tablets in the intrinsic record are described in other Gilead patents, and nothing in the intrinsic record of the ’846 Patent even remotely suggests that a POSA would understand that such a tablet might be considered “a multilayer tablet.” See Ex. 13, Muzzio Decl. ¶¶ 46–54. It represents a different type of “segregation” entirely.

Further, the patent that is broad enough to claim a monolayer tablet with all three active ingredients is U.S. Patent No. 11,744,802. (See Ex. 16 (’802 Patent), claim 1 (claiming simply a “tablet” with all three active ingredients included). The ’802 Patent was prosecuted after Gilead was made aware of Defendants’ respective non-infringing tablet designs, and Gilead then (while this case has been pending) successfully removed the term “multilayer” from that patent’s claims. See D.I. 1, ¶¶ 82–83 (referring to Cipla’s Detailed Statement), and ¶¶ 69–70 (referring to Laurus’s Detailed Statement). There is no reason to re-write the ’846 Patent claims to encompass essentially the same claim scope as Gilead secured (from the Patent Office) by prosecuting the continuation application that resulted in the ’802 Patent.

Gilead’s Reply Brief also holds firm to its central *straw man* fallacy, repeating again that Defendant’s construction of “a multilayer tablet” seeks to import limitations into the claims from exemplary embodiments described in the specification. As explained in Defendants’ Responsive Brief (and Dr. Muzzio’s Declaration), this is simply not true. Defendants employ the phrase “at least a bilayer tablet” to convey (effectively) the same definition as Gilead offers in the first clause of its construction, which is “a tablet with two or more layers.” Each illustration provided by Gilead in its Reply brief are tablets that would be within the scope of the phrase: “at least a bilayer

tablet.” Each of the illustrations in Gilead’s Reply has two or more layers. None of the hypothetical embodiments illustrated in Gilead’s brief are monolayer tablets, and none are excluded from the claim by Defendants’ construction.

The illustration on page 20 of Gilead’s reply, with “one component concentrated on one side and a second concentrated on the other side” is merely another example of a bilayer tablet configuration. Gilead apparently believes otherwise, contending this hypothetical embodiment lacks a “well-defined” boundary between both components. Defendants take no position on whether a well-defined boundary is required to be a “layer.” This is a new argument, not presented before by Gilead in the claim construction proceedings to date. However, the specification generally defines “segregation” to be a function of keeping components “physically discrete” from each other, “such that the presence of one component...does not substantially affect the stability in storage of the other component[s].” Ex. 13, Muzzio Decl., Ex. B (’846 Patent), 55:53–58. Whether two layers not separated by a “well-defined” boundary allows components to be “physically discrete” from one another is not an issue for claim construction. Moreover, individual granules mixed together and compressed into a monolayer tablet, with or without “well-defined boundaries,” are not layers.

The claims of the ’846 Patent were prosecuted to capture the segregation of the claimed active ingredients by layering in a multilayer tablet configuration. This is the only concept upon which Gilead was granted the ’846 Patent. *See* Ex. 13, Muzzio Decl., Ex. C (’846 File Wrapper) at BICANDA000006422–25 (applicant explaining to the examiner “a bilayer tablet formulation... results in approximately 30% higher” total bictegavir exposure); *and* BICANDA00006507 (final notice of allowance).

This Court should reject Gilead's invitation to so dramatically expand the scope of the issued claims of the '846 Patent by means of claim construction.

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