20IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE UNITED STATES OF AMERICA,	)	
	)	
Plaintiff/Counterclaim Defendant,	)	
	)	
v.	)	
	)	
GILEAD SCIENCES, INC.,	)	C.A. No. 19-2103 (MN)
	)	
Defendant/Counterclaim Plaintiff,	)	
	)	
and GILEAD SCIENCES IRELAND UC,	)	
	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 22nd day of October 2021:

IT IS HEREBY ORDERED that the disputed claim terms of U.S. Patents Nos. 9,044,509 ("the '509 Patent"), 9,579,333 ("the '333 Patent"), 9,937,191 ("the '191 Patent"), and 10,335,423 ("the '423 Patent") (collectively, "the Patents-in-Suit") are construed as follows:

1. the preamble reciting "[a] process of protecting a primate host from a self-replicating infection by an immunodeficiency retrovirus" is limiting and means "a process which allows a primate host to remain serologically negative and negative in response to a polymerase chain reaction (PCR) testing for viral genome when those tests are done" ('509 Patent, cl. 1; '333 Patent, cl. 1; '191 Patent, cl. 1; '423 Patent, cl. 1);

2. the preamble reciting "[a] process for inhibiting establishment of a human immunodeficiency virus self-replicating infection of human immunodeficiency virus infection in a human" is limiting and means "a process for inhibiting establishment of a human immunodeficiency virus self-replicating infection in a human" ('509 Patent, cl. 12; '333 Patent, cl. 12; '191 Patent, cl. 13; '423 Patent, cl. 12);

3. "thereby protecting the primate host from infection with the immunodeficiency retrovirus" is limiting and means "the primate host remains serologically negative and negative in response to a polymerase chain reaction (PCR) testing for viral genome while receiving the administration" ('509 Patent, cl. 1; '333 Patent, cl. 1; '191 Patent, cl. 1; '423 Patent, cl. 1);

4. "thereby inhibiting the establishment of the self-replicating infection with the immunodeficiency virus in the human" is limiting and means "[t]he human remains negative for the immunodeficiency virus while receiving the administration" ('509 Patent, cl. 12; '333 Patent, cl. 12; '191 Patent, cl. 13; '423 Patent, cl. 12);

5. "tenofovir ester" means "an ester in which one of the components is tenofovir" ('509 Patent, cl. 12)

6. "prior to an [the] exposure" requires an exposure, which means "contact between an immunodeficiency retrovirus and a host" ('509 Patent, cl. 1, 7; '333 Patent, cl. 1, 7; '191 Patent, cl. 1, 7; '423 Patent, cl. 1, 7); and

7. "prior to an [the] exposure" means "prior to engaging in activity that could result in an exposure" ('509 Patent, cl. 13; '333 Patent, cl. 13; '191 Patent, cl. 13; '423 Patent, cl. 12).

The parties briefed the issues, (*see* D.I. 108), and submitted a Joint Claim Construction Chart containing intrinsic evidence, (*see* D.I. 75, 114). The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim terms, heard oral argument, (*see* D.I. 118), and applied the following legal standards in reaching its decision.

I. LEGAL STANDARDS

A. Claim Construction

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). "[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning

to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

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 Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the

meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. 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*, 90 F.3d at 1583).

II. THE COURT'S RULING

The Court's rulings regarding the disputed claim terms of the Patents-in-Suit were announced from the bench at the conclusion of the hearing as follows:

> . . . Thank you for the arguments earlier today. At issue we have four patents in one family[1] and seven disputed claim terms.
>
> I am prepared to rule on each of the disputes. I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patents in dispute. I have also reviewed the portions of

[1] As the Patents-in-Suit share a common specification, all citations to the specification will be to the '509 Patent.

the prosecution histories, IPRs, scientific publications, dictionaries, and expert declarations included in the Joint Appendix. There was full briefing on each of the disputed terms and a technology tutorial submitted by each of the parties. And as an aside I want to say that Gilead's tutorial was one of the best tutorials I've had submitted to me in terms of explaining in a way that I could understand what the technology is. So thank you for that. We have also had argument here today. All of that has been carefully considered.

As to my rulings, I am not going to read into the record my understanding of claim construction law. I have a legal standard section that I have included in earlier opinions, including recently in *Roche Diabetes Care, Inc. v. Insulet Corp.*, C.A. No. 20-825. I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.

Neither party has suggested a definition of the person of ordinary skill in the art, but no party suggests that the differences are relevant to the issues currently before me.

Now the disputed terms.

The first term is "[a] process of protecting a primate host from a self-replicating infection by an immunodeficiency retrovirus." This term is the preamble of claim 1 of the '509, '333, '191, and '423 Patents, and the parties dispute whether that preamble is limiting. Plaintiff asserts that it is limiting and Defendant asserts that it is not.

Here, I agree with Plaintiff that the preamble is limiting.

"Whether to treat a preamble as a limitation is a determination resolved only on review of the entire patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim."[2] Here, the entirety of the patent suggests that this preamble, discussing protection from an immunodeficiency retrovirus, "is necessary to give life, meaning, and vitality" to the claim.[3]

The specification repeatedly uses the words "protect," "protection," and "protecting." The Summary of the Invention describes a process

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2 *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1309 (Fed. Cir. 2004) (cleaned up).

3 *Id.* (cleaned up).

for "protecting a primate host,"[4] and goes on to state that "protection is achieved,"[5] a particular regime is "effective in providing protection,"[6] and describes a combination dose "sufficient to protect a primate host."[7] Each of these examples refers to protection from a self-replicating infection by an immunodeficiency virus, which is the same language as the preamble at issue. The specification also discusses protection from such self-replicating infections numerous other times throughout the description and the examples. These repeated references to "protection" suggest that the preamble gives life, meaning, and vitality to the claims, and is therefore limiting.

Furthermore, the preamble provides antecedent basis for language in the claims. The preamble references "an immunodeficiency retrovirus" and the claim language references "the immunodeficiency retrovirus."[8] This confirms that the preamble should be construed as limiting.

Defendant argues that construing the preamble as limiting would make these claims redundant with other claims. Defendant points to claim 11 of each patent, which adds a limitation that the process of the independent claim must result in "an absence of persistent viremia and seroconversion of the primate host," and notes that this language is consistent with the definition of "protection" given in Example 7 of the patents. That definition, however, is not used consistently throughout the patents. Therefore, claim 11 adds an additional, more stringent requirement for "protection."

Defendant argues that the meaning of "protection" is ambiguous.[9] The specification, however, states that "'protection' as used in the context of a host primate response to an immunodeficiency virus challenge is defined by the host primate being serologically negative and negative in response to a polymerase chain reaction (PCR)

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4 ('509 Patent col. 2 ll. 9–10).

5 ('509 Patent col. 2 l. 11).

6 ('509 Patent col. 2 ll. 19–20).

7 ('509 Patent col. 2 ll. 35–36).

8 ('509 Patent col. 12 ll. 39–42).

9 (D.I. 108 at 17.)

testing for viral genome."[10] It is well-settled that the specification may define a claim term and that, when it does, "the inventor's lexicography governs."[11] "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."[12] Consistent with that express definition of "protection," I am going to construe the preamble to mean "a process which allows a primate host to remain serologically negative and negative in response to a polymerase chain reaction (PCR) testing for viral genome when those tests are done."

The second term is "[a] process for inhibiting establishment of a human immunodeficiency virus self-replicating infection of human immunodeficiency virus infection in a human," which is the preamble of claim 12 of the '509, '333, and '423 Patents and claim 13 of the '191 Patent. Plaintiff contends that the preamble is limiting, and that it should be judicially corrected to read "[a] process for inhibiting establishment of a human immunodeficiency virus self-replicating infection in a human." Defendant asserts that the preamble is nonlimiting and argues that judicial correction is inappropriate.

The parties seem to agree that the analysis governing whether this term is limiting is the same as for the first set of preambles. Therefore, as I have already explained, I conclude that this preamble is limiting.

As to the issue of judicial correction, I am not going to correct the term at this time. Judicial correction of claims is a "narrow remedy to be used sparingly."[13] As Defendant pointed out, the purportedly "obvious" error[14] was made repeatedly without anyone actually

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10 ('509 Patent col. 4 ll. 3–7).

11 *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005).

12 *Cont'l Circuits LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019) (quoting *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). *See Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015).

13 *Vifor (Int'l) AG v. Mylan Lab'ys Ltd.*, No. CV 19-13955 (FLW), 2021 WL 1608908, at *2 (D.N.J. Apr. 26, 2021).

14 (D.I. 108 at 20).

noticing it.[15] And that suggests that perhaps it is subject to reasonable debate and not properly corrected.

I note that Defendant suggests that this term may be the subject of a future indefiniteness dispute, which the parties have agreed to reserve until the summary judgment or trial stage of this action.[16] If Defendant ultimately chooses to use its limiting summary judgment pages or trial time on such an indefiniteness argument, that is its decision. But at this stage, I am also not convinced that what Plaintiff views as an error significantly changes the meaning of the term.

So I will not judicially correct the term but I will construe the term consistently with Plaintiff's proposed language: "a process for inhibiting establishment of a human immunodeficiency virus self-replicating infection in a human."

The third term is "thereby protecting the primate host from infection with the immunodeficiency retrovirus."[17] Plaintiff argues that this "thereby" clause is limiting, and should be construed as "[t]he primate host remains negative for the immunodeficiency retrovirus while receiving the administration." Defendant contends that the clause is non-limiting.

The parties' arguments as to this term are the same as for the preambles. Therefore, as I have already explained, I conclude that this term is limiting.

As to the construction of this term, Defendant raises two issues with Plaintiff's proposal.

First, Defendant argues that it is unclear from the specification or Plaintiff's proposal how long a primate host must remain negative for the retrovirus. I'll note that this sounds like an indefiniteness argument which the parties agreed to reserve until later. But at this stage, I agree with Plaintiff that the specification provides enough information about the effective time period that a POSA would know how long a host is protected from the administration. The Abstract notes that "[t]he administration is effective is provided . . .

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15 (D.I. 108 at 24–25 (noting three future filings repeating the alleged error); *see also* D.I. 108 at Appx1026, Appx1507, Appx1853).

16 (D.I. 76).

17 This term is in claim 1 of the '509, '333, '191, and '423 Patents.

within 24 hours of the exposure."[18] And the specification goes on to state that "a single dosage is administered to assure a therapeutically effective amount of NRTI and NtRTI persist in the primate host for a time of more than 12 hours after viral challenge,"[19] but that the dose is "preferably . . . administered within 12 hours prior to retroviral exposure and still more preferably often within 2 hours prior."[20] And it also explains that "an individual routinely subjected to retroviral exposure can be protected against the development of a self-replicating retroviral infection through administration of regular prophylactic doses."[21] On the record before me, I find that a POSA would be adequately informed as to how long the host will remain protected after receiving the administration.

The second issue raised by Defendant is that it is unclear what assay is used to determine whether the host is negative. In response to this point, Plaintiff argues that "either [serological or PCR] assay is appropriate to determine negativity."[22] The specification, however, defines protection as "the host primate being serologically negative *and* negative in response to a polymerase chain reaction (PCR) testing for viral genome,"[23] which suggests that a negative test must be obtained with both assays.

Therefore, consistent with that definition, I will construe this term to mean "the primate host remains serologically negative and negative in response to a polymerase chain reaction (PCR) testing for viral genome while receiving the administration." And to be clear, I am not saying that the claims require unnecessary testing to be done, but they do require a negative result on both tests if and when both tests are performed.

The fourth term is "thereby inhibiting the establishment of the self-replicating infection with the immunodeficiency virus in the

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18 ('509 Patent at (57)).

19 ('509 Patent at col. 5 ll. 12–15).

20 ('509 Patent at col. 5 ll. 16–19).

21 ('509 Patent col. 5 ll. 38–41)

22 (D.I. 108 at 34).

23 ('509 Patent col. 4 ll. 3–7 (emphasis added)).

human."[24] Plaintiff again argues that this clause is limiting, and that it should be construed as "[t]he human remains negative for the immunodeficiency virus while receiving the administration." Defendant asserts that the clause is non-limiting.

In the Joint Brief, neither party distinguished its argument as to this term from its arguments as to the third term. Therefore, for the same reasons as the previous term, I conclude that this term is limiting and will adopt Plaintiff's proposed construction of "[t]he human remains negative for the immunodeficiency virus while receiving the administration." As I have noted, however, the patent's definition of "protection" suggests that whether a host remains negative is based on both a serological and PCR assay if both are performed.

The fifth term is "tenofovir ester."[25] Plaintiff asserts that the term should be construed as "an ester-containing tenofovir derivative." Defendant contends that it should be construed as "a compound with a chemical structure that differs from tenofovir only in that one or both of the phosphonic acid O-H bonds in tenofovir is an O-C bond and the C is part of another group."

The dispute largely centers on whether the tenofovir ester must derive directly from tenofovir, or whether it may derive from some tenofovir derivative.

Here, I am going to construe the term to mean "an ester in which one of the components is tenofovir." And let me clarify that I mean that when the ester bonds are hydrolyzed one of the components is the compound recognized as tenofovir.

The claim that uses this term, claim 12 of the '509 Patent, requires administration of "a pharmaceutically effective amount of tenofovir or tenofovir ester." The government conceded today that the reference to tenofovir alone in that claim means the single compound tenofovir and does not include derivatives. That is consistent with how the specification uses the word tenofovir as well. Indeed, every time it is used, it refers to the compound itself, not derivatives.[26] Using that meaning of tenofovir then in the claim term "tenofovir ester," it refers to esterified tenofovir.

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24 This term is in claim 12 of the '509, '333, and '423 Patents and claim 13 of the '191 Patent.

25 This term is in claim 12 of the '509 Patent.

26 (*See, e.g.*, '509 Patent col. 6 l. 64 (distinguishing "tenofovir or TDF"); '509 Patent col. 9 ll. 19–20 (using the word "tenofovir" to refer to the exact compound, rather than a derivative), '509 Patent col. 11 l. 7 (same). *See also* '509 Patent col. 12 ll. 47–48 (claim

As the parties discussed in their briefing, the specification includes tenofovir in a list of several specific NtRTIs [nucleotide reverse transcriptase inhibitors] that may be used, and then explains that "the aforementioned specific NtRTIs [are] intended to include pharmaceutically acceptable salts, esters, ester salts, nitrile oxides, and prodrugs of any of the active agents."[27] Although this suggests that the specification may support broader claims that include other tenofovir derivatives or analogs or prodrugs, the claims at issue here do not claim tenofovir derivatives or analogs so broadly.

I am going to address the last two terms together as they have some similarities.

The sixth term is "prior to an [the] exposure."[28] Plaintiff argues that this term should be given its plain and ordinary meaning, which it contends is "[t]he administration step begins after selecting the primate host and before exposure of the primate host to the immunodeficiency retrovirus." Defendant argues that the term should be construed as "in advance of contact [of the primate host to the immunodeficiency retrovirus] that can result in infection."

The final term is "prior to [a] potential exposure."[29] Plaintiff argues that this term should be given its plain and ordinary meaning, which it contends is "[t]he administration step begins after selecting the human and before exposure of the human to the immunodeficiency retrovirus." Defendant argues that this term should be construed as "in advance of possible contact."

For both of these terms, I think we have a dispute about what constitutes "exposure." Here, exposure means "contact between the host and the immunodeficiency virus." This is supported by the intrinsic evidence. For example, the specification says that

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specifying "tenofovir or tenofovir disoprixil fumarate")). During prosecution, the patentee also did not use "tenofovir" to refer to derivatives, instead specifying that "tenofovir . . . and pharmaceutically acceptable derivatives thereof" were acceptable. (D.I. 108 at Appx618; *see also id.* at Appx630 (specifying "tenofovir pro-drug or tenofovir")).

27 ('509 Patent col. 5 l. 66 – col. 6 l. 2; *see also* '509 Patent col. 4 ll. 31–36 (explaining that "pharmaceutically acceptable derivatives of active . . . NtRTIs . . . in the present invention include salts such as alkali metal salts; esters such as acetate, butyrate, octanoate, palmitate, chlorobenzoates, benzoates, C1-C6 benzoates, succinates, and mesylate; salts of such esters; and nitrile oxides.")).

28 This term is in claims 1 and 7 of the '509, '333, '191, and '423 Patents.

29 This term is in claim 13 of '509, '333, and '191 Patents and claim 12 of the '423 Patent.

"exposure routes are characterized by a small number of *retrovirus particles* being transferred to the new primate host."[30] Similarly, in the prosecution history, when distinguishing the Keller reference, the patentee explained that "one of ordinary skill in the art recognizes from the specification that the term 'exposure' is initial contact between an immunodeficiency retrovirus and a host."[31]

The next issue is whether the claims require the primate host to actually be exposed to the virus. For the term "prior to an exposure," the answer is yes. This is consistent with, for example, claim 7 of the '509 Patent, which adds the limitation that the combination of drugs is "administered . . . prior to rectal and/or vaginal exposure of the primate host to the immunodeficiency retrovirus."[32] This suggests actual contact with the virus, not simply being in the proximity of it.

As to the "prior to a potential exposure" term, I find that those claims do not require the host to actually be exposed, but rather contemplate that the host engages in activity that has the potential to lead to exposure. This is supported by the claims. For example, in the '509 Patent the "prior to potential exposure" language appears only in dependent claim 13. The only limitation added by that dependent claim is that "the combination is administered prior to a potential exposure of the primate host to the human immunodeficiency retrovirus."[33] Thus, the primate host must engage in some activity in order for this claim to have meaning.[34] As Defendant's expert

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30 ('509 Patent col. 3 ll. 25–29 (emphasis added); *see also* '509 Patent col. 7 l. 64 – col. 8 l.1 (describing exposure of rhesus macaques); '509 Patent col. 9 ll. 5–11 (same); '509 Patent col. 9 ll. 39–40 (same)).

31 (D.I. 108 at Appx288; *see also* D.I. 108 at Appx 290 (arguing during prosecution history that "[a]pplicant maintains that the term 'exposure' is directed to initial contact between a host and a virus")).

32 ('509 Patent cl. 7; *see also* '509 Patent cl. 10, 15; '423 Patent cl. 7, 10, 14, 15; '333 Patent cl. 7, 10, 15 Cite claim 7; '191 Patent cl. 7, 10, 15, 19).

33 ('509 Patent cl. 13; '333 Patent cl. 13, 16).

34 The claims confirm that "potential exposure" refers to activity that could result in contact with the virus. For example, although independent claim 12 of the '423 Patent requires that the drug combination be administered "prior to potential exposure", dependent claim 17 further requires that "the potential exposure . . . comprises sexual intercourse, medical worker skin puncture inoculation, hypodermic needle sharing, or blood transfusion. ('423 Patent cl. 12, 17; *see* '191 Patent cl. 16 (same); *see also* '509 Patent cl. 17 (listing same

opined, a "potential exposure" can occur when, for example, it is unknown "whether a bodily fluid . . . that the host had contact with is indeed a source of HIV" and a POSA would understand that the antiviral agents in the host's body are intended to prevent replication of virus particles "if in fact there were contact with any such particles."[35]

Therefore, I will construe "prior to an exposure" to require an exposure, which is "contact between an immunodeficiency retrovirus and a host."

And I will construe "prior to a potential exposure" to mean "prior to engaging in activity that could result in an exposure."

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge

examples of potential exposure for claim to be performed following a potential exposure); '333 Patent cl. 16 (same)).

35 (D.I. 108 at Appx7175–76).