

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC., )  
)  
Plaintiff, )  
)  
v. )  
)  
APOTEX, INC., LUPIN LIMITED, ) C.A. No. 20-189-MN  
LAURUS LABS LIMITED, SHILPA )  
MEDICARE LIMITED, SUNSHINE LAKE )  
PHARMA CO., LTD., NATCO PHARMA )  
LIMITED, CIPLA LIMITED, MACLEODS )  
PHARMACEUTICALS LTD., HEREO )  
USA INC., HETERO LABS LIMITED )  
UNIT-V, and HETERO LABS LIMITED, )  
)  
Defendants. )

**MEMORANDUM ORDER**

At Wilmington this 26th day of May 2021:

IT IS HEREBY ORDERED that the claim term of U.S. Patent Nos. 7,390,791 (“the ’791 Patent”) and 7,803,788 (“the ’788 Patent”) with agreed-upon construction is construed as follows (*see* D.I. 223)<sup>1</sup>:

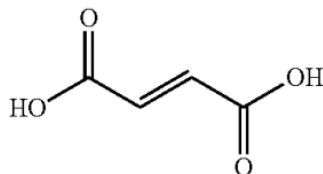
1. “diastereomerically enriched” means “enriched relative to all other diastereomers” (’791 Patent – Claims 1, 4, 7, & 8; ’788 Patent – Claims 1–7).

Further, as announced at the hearing on May 20, 2021, IT IS HEREBY ORDERED that the disputed claim terms of U.S. Patent Nos. 8,754,065 (“the ’065 Patent”) and 9,296,769 (“the ’769 Patent”) are construed as follows:

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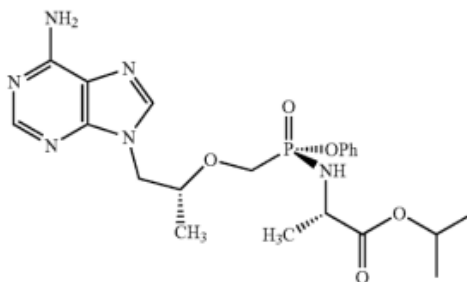
<sup>1</sup> The Court refers to the parties’ Joint Claim Construction Brief, D.I. 223, dated April 29, 2021.

1. “tenofovir alafenamide hemifumarate” means “a hemifumarate form of tenofovir alafenamide” (’065 Patent – Claims 1, 4, 6, 27, & 30; ’769 Patent – Claim 1).
2. “tenofovir alafenamide monofumarate” means “a monofumarate form of tenofovir alafenamide” (’769 Patent – Claims 1–3).
3. “fumaric acid” means



and includes ionized and/or associated forms of fumaric acid (’065 Patent – Claims 6–9, 27, & 30; ’769 Patent – Claims 4–5).

4. “tenofovir alafenamide” means



and includes ionized and/or associated forms of tenofovir alafenamide (’065 Patent – Claims 6–9, 27, & 30; ’769 Patent – Claims 4–5).

The parties briefed the issues (*see* D.I. 223) and submitted an appendix containing both intrinsic and extrinsic evidence, including expert declarations (*see* D.I. 224; D.I. 225). The Court carefully reviewed all submissions in connection with the parties’ contentions regarding the disputed claim terms, heard oral argument (*see* D.I. 235), and applied the following legal standards in reaching its decision.

## **I. LEGAL STANDARD**

“[T]he ultimate question of the proper construction of the patent [is] a question of law,” although subsidiary fact-finding is sometimes necessary. *Teva Pharm. 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 '065 and '769 Patents were announced from the bench at the conclusion of the hearing. The Court's rulings are as follows:

At issue are four disputed claim terms in two patents, U.S. Patent Nos. 8,754,065 and 9,296,769, which collectively I'll refer to as "the Hemi patents." The '065 and '769 patents incorporate by reference the two prodrug patents asserted in this case, U.S. Patent Nos. 7,390,791 and 7,803,788.

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 and the evidence submitted by the parties in the almost 1,400 pages of appendices, which included expert declarations. There was full briefing on each of the disputed terms, and each party submitted a technology tutorial that we have reviewed. There has been argument here today. All of that has been carefully considered.

Now as to my rulings. As an initial matter I am not going to read into the record my understanding of claim construction law generally. I have a legal standard section that I have included in earlier opinions including recently in *Purewick Corporation v. Sage Products, LLC*, Civil Action No. 19-1508. I incorporate that law and adopt it into my rulings and will also set it out in the order that I issue.

As to a person of ordinary skill in the art, the parties through their experts have offered slightly different definitions. The parties, however, have not asserted that the differences are relevant to the issues before me today.

Now the disputed terms.

The first term is "tenofovir alafenamide hemifumarate" or "TAF Hemi" for short. This term is in claims 1, 4, 6, 27, and 30 of the '065 patent and claim 1 of the '769 patent. Plaintiff proposes the construction, "a hemifumarate form of tenofovir alafenamide." Defendants propose, "a hemifumarate salt of tenofovir alafenamide." The crux of the dispute is whether the term is limited

to salts, or whether other forms, such as co-crystals, are encompassed.<sup>[2]</sup> Here, I agree with Plaintiff.

Plaintiff's construction finds support in the specifications of the '065 and '769 patents,<sup>[3]</sup> which repeatedly refer to a hemifumarate form of tenofovir alafenamide or "TAF." In the Summary of the Invention, the patents state: "Described is a hemifumarate form of . . . tenofovir alafenamide. The hemifumarate form of tenofovir alafenamide is also referred to herein as tenofovir alafenamide hemifumarate."<sup>[4]</sup> The written description repeatedly states that the patented invention is a "hemifumarate form of tenofovir alafenamide," compared to a "monofumarate form" of tenofovir alafenamide.<sup>[5]</sup> The written description in column 4 also depicts preparation of TAF Hemi. In the figure, the TAF Hemi is shown with a dot between the TAF and the fumaric acid. Defendants' expert recognized that both salts and co-crystals can be depicted using such a structural formula with a dot.<sup>[6]</sup> Thus, the patent specification, which is "the single best guide to the meaning of a disputed term,"<sup>[7]</sup> supports Plaintiff's construction.

Defendants argue that a person of ordinary skill would recognize that the terms "hemifumarate" and "monofumarate"

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<sup>2</sup> (See D.I. 223 at 15, 17).

<sup>3</sup> The written descriptions of the Hemi patents are substantially identical. For the sake of simplicity, the Court will cite to only one patent's written description as appropriate.

<sup>4</sup> ('065 patent at 1:31–37).

<sup>5</sup> (See, e.g., *id.* at 3:39–41 ("In one embodiment, there is provided a hemifumarate form of tenofovir alafenamide (i.e., tenofovir alafenamide hemifumarate)."); 4:64–66 ("One major advantage of the hemifumarate form of tenofovir alafenamide over the monofumarate form is its exceptional capability to purge [diastereomeric impurities]."); 5:6–10 ("Other major advantages of tenofovir alafenamide hemifumarate over the monofumarate form include improved thermodynamic and chemical stability . . . , superior process reproducibility, superior drug product content uniformity, and a higher melting point."); 8:44–9:24 (describing preparation of tenofovir alafenamide hemifumarate via selective crystallization wherein the final step "afford[s] the final compound of the hemifumarate form of tenofovir alafenamide as a white to off-white powder."))

<sup>6</sup> (D.I. 225-2, Ex. 8 ¶¶ 82–83).

<sup>7</sup> *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005).

identify specific salts of TAF.<sup>[8]</sup> The parties generally agree that a salt is a compound created through the ionic interaction between positively charged cations and negatively charged anions. Although the word “salt” does not appear anywhere in the Hemi patents – except in the titles of certain “Other Publications” – Defendants assert that “[p]harmaceutical chemists have long appreciated that the suffix ‘-ate’ (appearing here in the root word ‘fumarate’) describes ‘anions formed by the loss of a proton from an acid,’ and salts of acids having a name ending in ‘-ic.’”<sup>[9]</sup> Thus, Defendants contend, a POSA would have understood “tenofovir alafenamide hemifumarate” to refer to a salt formed of tenofovir alafenamide cation and fumaric acid anion in a 2:1 ratio (hence, “hemi-”).

Correspondence with the FDA<sup>[10]</sup> as well as articles submitted in connection with the briefing,<sup>[11]</sup> however, use the term hemifumarate to include things other than salts, such as co-crystals. Thus, the word “hemifumarate” does not necessarily imply a salt as a matter of nomenclature.

Defendants also argue that the intrinsic evidence and prosecution history support their construction. The ’065 and ’769 patents claim priority from U.S. Provisional Application No. 61/524,224 [(“the ’224 application”)], which discloses a pharmaceutically acceptable coformer, “e.g. a co-crystal complex or a salt,” of fumaric acid and TAF.<sup>[12]</sup> The parties generally agree that in a co-crystal complex, the components interact via non-ionic associations.<sup>[13]</sup> Defendants assert that the deliberate omission of

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<sup>8</sup> (D.I. 223 at 18).

<sup>9</sup> (*Id.* at 19).

<sup>10</sup> (D.I. 225-31, Ex. 9R; D.I. 225-33, Ex. 11; D.I. 225-34, Ex. 12 (paragraph IV letters submitted by two Defendants)).

<sup>11</sup> (*See, e.g.*, D.I. 225-15, Ex. 6I; D.I. 225-28, Ex. 9O).

<sup>12</sup> (D.I. 224-9, Ex. 6C at 3:20–4:30).

<sup>13</sup> Plaintiff’s expert states, “[c]o-crystals generally lack a complete proton transfer from the acid to the base. Thus, a co-crystal is typically characterized as a form in which the components associate through non-ionic bonding, such as hydrogen bonding.” (D.I. 224-6, Ex. 6 ¶ 103 (citation omitted)). Defendants’ expert offers, “unlike salts, where the components in a crystal lattice are in an ionized state, a co-crystal’s components are in a

the word “co-crystal” from the ’065 and ’769 patents “establishes that the inventors no longer considered co-crystals to be pertinent to the claimed invention.”<sup>[14]</sup> The Hemi patents, however, also omit any reference to “salt” or any other specific composition type, in favor of hemifumarate “forms” generally. Thus, I disagree with Defendants’ inference that the asserted patents, read in light of the ’224 application, disclose only hemifumarate salts of TAF.

Defendants also contend that during prosecution of the ’065 patent, the applicant adopted the patent examiner’s characterization of “tenofovir alafenamide hemifumarate” as a salt. The examiner rejected dependent claims 2–5, which originally recited embodiments of TAF Hemi with close to a 0.5 ratio of fumaric acid to tenofovir alafenamide.<sup>[15]</sup> The examiner stated, “a hemifumarate is a salt of a compound at a 2:1 stoichiometric ratio of compound to fumaric acid . . . . As such, claims 2–5 fail to further limit claim 1 because ‘tenofovir alafenamide hemifumarate’ necessarily defines a compound having a ratio of fumaric acid to tenofovir alafenamide of about 0.5.”<sup>[16]</sup> In response, the applicant amended claims 2–5, issued as claims 6–9, to recite a composition comprising the TAF Hemi of claim 1.<sup>[17]</sup> Thus, the applicant adopted the examiner’s view that “hemifumarate” denotes a 0.5 ratio of fumaric acid to another component. The amendment does not clearly and unmistakably show applicant’s acquiescence to the examiner’s characterization of hemifumarate as a salt.<sup>[18]</sup> Nor is it sufficient to supersede the patents’ clear lexicography, and thus I adopt

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neutral state and interact via non-ionic interactions.” (D.I. 225-2, Ex. 8 ¶ 57 (quotation marks and citation omitted)).

14 (D.I. 223 at 23).

15 (D.I. 224-17, Ex. 6K at 5).

16 (*Id.*).

17 (D.I. 224-18, Ex. 6L at 2).

18 *See 3M Innovative Props. Co v. Avery Dennison Corp.*, 350 F.3d 1365, 1373–74 (Fed. Cir. 2003) (“An applicant’s silence in response to an examiner’s characterization of a claim does not reflect the applicant’s clear and unmistakable acquiescence to that characterization if the claim is eventually allowed on grounds unrelated to the examiner’s unrebutted characterization); *TorPharm Inc. v. Ranbaxy Pharm., Inc.*, 336 F.3d 1322, 1331 (Fed. Cir. 2003) (“A patentee is not required to fight tooth and nail every possibly adverse thought an examiner commits to paper.”).



Plaintiff's construction that TAF Hemi is a "hemifumarate form of tenofovir alafenamide."<sup>[19]</sup>

The second term, closely related to the first term, is "tenofovir alafenamide monofumarate" ("TAF Mono") in claims 1–3 of the '769 patent. Plaintiff proposes the construction, "a monofumarate form of tenofovir alafenamide." Defendants propose, "a monofumarate salt of tenofovir alafenamide." Again, the crux of the dispute is whether the term is limited to salts, and again, I adopt Plaintiff's construction.

Claims 1–3 of the '769 patent recite compositions "comprising tenofovir alafenamide hemifumarate, wherein the composition comprises [certain maximum amounts] of tenofovir alafenamide monofumarate." Although the Hemi patents do not expressly define "tenofovir alafenamide monofumarate" as they do "tenofovir alafenamide hemifumarate," the patents use the two terms consistently, contrasting the "monofumarate form" from the "hemifumarate form of tenofovir alafenamide."<sup>[20]</sup> The parties also agree that the "monofumarate" term should be construed consistently with the preceding "hemifumarate" term.<sup>[21]</sup> Finding no reason to treat the two terms differently, I will adopt the construction, "monofumarate form of tenofovir alafenamide."

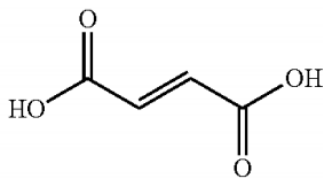
The third term is "fumaric acid" in claims 6–9, 27, and 30 of the '065 patent and claims 4 and 5 of the '769 patent. Plaintiff proposes that the term corresponds to a particular chemical structure,

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<sup>19</sup> Defendants also rely on the '791 patent, which is incorporated by reference in the Hemi patents. (*See* '065 patent at 1:16–17). The '791 patent, however, simply references a "fumarate salt" as a preferred embodiment and does not define the term "fumarate" to mean a salt. ('791 patent at 4:33–34).

<sup>20</sup> (*See, e.g.*, '769 patent at 4:54–56 ("One major advantage of the hemifumarate form of tenofovir alafenamide over the monofumarate form is its exceptional capability to purge [diastereomeric impurities]."), 4:63–67 ("Other major advantages of tenofovir alafenamide hemifumarate over the monofumarate form include improved thermodynamic and chemical stability . . . , superior process reproducibility, superior drug product content uniformity, and a higher melting point."), 10:59–65, 11:26–33, 11:35–39).

<sup>21</sup> (*See* D.I. 223 at 45–47).



“including its ionized and/or associated forms.” Defendants propose the construction, “the compound having the chemical name *trans*-1,2-ethylenedicarboxylic acid” and having the same chemical structure as that provided by Plaintiff. The crux of the parties’ dispute is whether “fumaric acid” includes its ionized and/or associated forms.<sup>[22]</sup> Here again, I agree with Plaintiff.

The asserted patents do not offer a definition of “fumaric acid,” and both sides assert that its proposed construction is the plain and ordinary meaning of the term according to a POSA. The claims recite “fumaric acid” as a starting material for preparing TAF Hemi. For example, claim 27 of the ’065 patent recites “[a] method for preparing tenofovir alafenamide hemifumarate comprising admixing a) aprotic organic solvent; b) *fumaric acid*; c) tenofovir alafenamide; and d) one or more seeds of tenofovir alafenamide hemifumarate; and crystallizing additional tenofovir alafenamide hemifumarate.”<sup>[23]</sup> When used as a starting material, fumaric acid is non-ionized and unassociated.<sup>[24]</sup> The ’065 patent also discloses, “[i]n one embodiment, tenofovir alafenamide hemifumarate consists of *fumaric acid* and tenofovir alafenamide in a ratio of  $0.5 \pm 0.1$ .”<sup>[25]</sup> When appearing as a component of TAF Hemi, fumaric acid is ionized or otherwise associated with the tenofovir alafenamide component. Therefore, a POSA would understand that “fumaric

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<sup>22</sup> Plaintiff argues that including the chemical name is unnecessary and potentially narrowing because fumaric acid has other names. (D.I. 223 at 48 n.9). Defendants do not address this argument. The parties focus their arguments on whether ionized and/or associated forms are included. Because it is not apparent that the chemical name informs that dispute, or any other dispute over claim scope, the Court will not include a chemical name in the construction.

<sup>23</sup> (’065 patent at claim 27 (emphasis added). *See also id.* at claim 30.).

<sup>24</sup> (*See* D.I. 223 at 49, 52).

<sup>25</sup> (’065 patent at 3:44–46 (emphasis added). *See also id.* at 9:48–51 (“Tenofovir alafenamide hemifumarate from Example 3 consists of [TAF] and one-half an equivalent of fumaric acid.”)).

acid” in the patents describes both non-ionized/unassociated fumaric acid and ionized/associated fumaric acid.<sup>[26]</sup>

Defendants’ construction would lead to the nonsensical result that TAF Hemi contains no fumaric acid, when the Hemi patents state that TAF Hemi “consists of fumaric acid and tenofovir alafenamide in a ratio” of about 0.5. Defendants argue that 0.5 is not the ratio of components of TAF Hemi, but “the stoichiometric ratio” of free acid and free base starting materials, which is not necessarily the ratio of acid and base found in the resulting salt.<sup>[27]</sup> The ’065 patent only once uses “stoichiometric ratio or mole ratio” and does not define “stoichiometric ratio” as applying only to starting materials.<sup>[28]</sup> Defendants’ contention that the ratio describes the starting materials of TAF Hemi does not override the written description’s express disclosure that “tenofovir alafenamide hemifumarate consists of fumaric acid and tenofovir alafenamide in a ratio of [about 0.5].”

Defendants also contend that nothing in the patent claims says that TAF Hemi contains “fumaric acid” rather than fumarate anion.<sup>[29]</sup> Claims 6–9 of the ’065 patent recite “[a] composition comprising tenofovir alafenamide hemifumarate” having close to a 0.5 ratio of fumaric acid to TAF. Defendants argue that this ratio can be interpreted to apply to the claimed composition, excluding TAF Hemi. That argument, however, is difficult to square with the parties’ and the patent examiner’s understanding that the 0.5 ratio is dictated by the “hemi–” prefix of TAF Hemi.<sup>[30]</sup> Under Defendants’

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<sup>26</sup> Defendants correctly note that the Hemi patents do not include the words “ionized” and “associated.” (D.I. 223 at 50). That omission, however, is consistent with the patents’ description of TAF Hemi and TAF Mono as “forms” rather than “salts” of fumarate. Whereas “salt” would narrowly suggest an ionic interaction between fumarate anion and tenofovir alafenamide cation, “form” appears to be agnostic to the type of interaction or association between components.

<sup>27</sup> (D.I. 223 at 54 (citing D.I. 225-2, Ex. 8 ¶¶ 83, 89)).

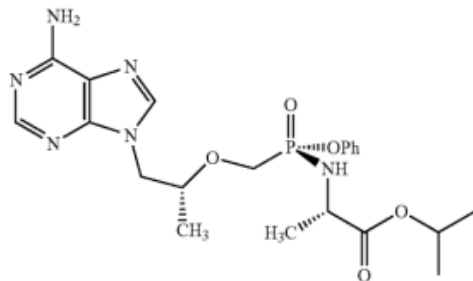
<sup>28</sup> “This [hemifumarate] form may have a ratio (i.e., a stoichiometric ratio or mole ratio) of fumaric acid to tenofovir alafenamide of  $0.5\pm 0.1$ ,  $0.5\pm 0.05$ ,  $0.5\pm 0.01$ , or about 0.5, or the like.” (’065 patent at 3:41–43).

<sup>29</sup> (D.I. 223 at 52–53).

<sup>30</sup> The patent examiner rejected original claims 2–5 of the ’065 patent for failing to narrow claim scope because independent claim 1 recited a “hemifumarate” and dependent claims 2–5 recited hemifumarates with close to a 0.5 equivalent of fumaric acid. (D.I. 224-17,

proposed construction, everything in the claimed composition except TAF Hemi would have the claimed “hemi” ratio, while TAF Hemi itself, containing no fumaric acid and no tenofovir alafenamide, would have a ratio of 0.

The fourth term is “tenofovir alafenamide” in claims 6–9, 27, and 30 of the '065 patent and claims 4 and 5 of the '769 patent. As with “fumaric acid,” Plaintiff proposes that the term “tenofovir alafenamide” corresponds to a certain chemical structure,



“including its ionized and associated forms.” Defendants propose the construction, “the compound having the chemical name 9-[(R)-2-[[[(S)-[(S)-1-(isopropoxycarbonyl)ethyl]amino]phenoxyphosphinyl]methoxy]propyl]adenine” and having the same chemical structure as that provided by Plaintiff. I will adopt Plaintiff’s construction.

As an initial matter, the '065 and '769 patents offer a definition of the disputed term, stating, “[t]he name for 9-[(R)-2-[[[(S)-[(S)-1-(isopropoxycarbonyl)ethyl]amino]phenoxyphosphinyl]methoxy]propyl]adenine is tenofovir alafenamide.”<sup>[31]</sup> The patents, however, also define tenofovir alafenamide as “L-alanine, N-[(S)-[(1R)-2-(6-amino-9H-purin-9-yl)-1-methylethoxy]methyl]phenoxyphosphinyl]-, 1-methylethyl ester.”<sup>[32]</sup> Plaintiff argues that Defendants’ choice of the first chemical name over the second is unexplained and potentially

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Ex. 6K at 5). Defendants themselves state, “[t]he plain and ordinary meaning of ‘hemifumarate’ thus refers to a salt containing one-half equivalent of a fumarate anion . . . [to] one equivalent of the correspondent cation.” (D.I. 223 at 20).

<sup>31</sup> ('065 patent at 1:33–35).

<sup>32</sup> (*Id.* at 1:20–24).

narrowing.<sup>[33]</sup> Plaintiff does not dispute that the first chemical name is accurate but argues that adopting that name will not resolve the parties' dispute as to whether the term includes ionized and/or associated forms.<sup>[34]</sup> Because the parties agree on the chemical structure and principally argue what forms are encompassed, I will not adopt a chemical name into the construction of "tenofovir alafenamide."<sup>[35]</sup>

The crux of the parties' dispute is whether "tenofovir alafenamide" includes its ionized and/or associated forms. As with "fumaric acid," the Hemi patents recite "tenofovir alafenamide" as a starting material for preparing TAF Hemi.<sup>[36]</sup> The claims also recite "tenofovir alafenamide" as a component of a composition comprising TAF Hemi.<sup>[37]</sup> The written description also discloses "tenofovir alafenamide" as a component of TAF Hemi.<sup>[38]</sup> Thus, as with "fumaric acid," these disclosures suggest that "tenofovir alafenamide" includes both non-ionized/unassociated and ionized/associated forms, consistent with Plaintiff's proposed construction of the term.

  
The Honorable Maryellen Noreika  
United States District Judge

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<sup>33</sup> (D.I. 223 at 62 n.12, 68 n.14).

<sup>34</sup> Defendants argue that the chemical name describes a free base and not its ionized/associated forms, (D.I. 223 at 64), but that argument does not explain the choice of the first chemical name over the second.

<sup>35</sup> *Cf. O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." (citing *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997))).

<sup>36</sup> (*See, e.g.*, '065 patent at claim 27).

<sup>37</sup> (*See, e.g., id.* at claim 6).

<sup>38</sup> (*See, e.g., id.* at 3:44–48).