UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD ______

Paper 23

Date: March 4, 2024

SYNAFFIX B.V., Petitioner,

v.

HANGZHOU DAC BIOTECH CO., LTD., Patent Owner.

IPR2022-01531 Patent 10,131,682 C1

Before MICHAEL W. KIM, *Acting Deputy Chief Administrative Patent Judge*, JANET A. GONGOLA, *Vice Chief Administrative Patent Judge*, and JAMES A. WORTH, *Acting Senior Lead Administrative Patent Judge*.

WORTH, Acting Senior Lead Administrative Patent Judge.

DECISION Granting Rehearing; Decision on Rehearing 37 C.F.R. §§ 42.5, 42.71

I. INTRODUCTION

A. Background and Summary

On February 9, 2023, SynAffix B.V. ("Petitioner") filed a Petition (Paper 2) requesting an *inter partes* review of claims 1–17, 20, 21, 24–26, and 29–34 of U.S. Patent No. 10,131,682 C1 (Exs. 1001, 1002

(reexamination)). On May 26, 2023, Hangzhou DAC Biotech Co., Ltd. ("Patent Owner") filed a Preliminary Response. Paper 9. On July 11, 2023, Petitioner filed a Preliminary Reply. Paper 11. On July 19, 2023, Patent Owner filed a Preliminary Sur-Reply. Paper 14. On August 1, 2023, Petitioner filed a brief in response to Patent Owner's Preliminary Sur-Reply. Paper 15. On August 3, 2023, Patent Owner filed a further brief in response. Paper 16.

On August 22, 2023, the Board panel ("the panel" or "the original Board panel") issued a decision denying institution of *inter partes* review. Paper 17 ("the Decision" or "the prior Decision").

On September 21, 2023, Petitioner filed a request for Director Review. Paper 18 ("Request").

On November 16, 2023, the Director issued an Order delegating the Director Review of the Decision to a Delegated Rehearing Panel. Paper 19. Also on November, 16, 2023, the Board issued an Order identifying the Delegated Rehearing Panel as this panel. Paper 20.

On November 17, 2023, we issued an Order providing Patent Owner the option to file a response to Petitioner's Request, including on the issue of whether there is a prosecution history disclaimer. Paper 21. On November 22, 2023, we extended the deadline for a response. *See* Ex. 3003; Ex. 3004. On December 15, 2023, Patent Owner filed a response. Paper 22.

For the reasons set forth below, we grant rehearing, vacate the prior Decision, and remand to the panel for proceedings consistent with this opinion.

B. Illustrative Claim

Independent claim 1 is illustrative of the subject matter at issue in this proceeding, and is reproduced below:

1. A hydrophilic linker of formula (I)

$$Y - R_1 + Q - R_2 + T - R_3 + R_4 - Z$$

$$R_5 R_6$$
(I)

wherein:

Y represents a functional group that enables reaction of the hydrophilic linker with a cell-binding agent;

Q and T are either —
$$P(=O)(OM)$$
—, or — $S(O_2)$ —, or — $S(O)$ —;

m and n are integers from 0 to 5, but not 0 at the same time; provided that when m=1, n=0, Q is not P(=O)(OM)—; when n=1, m=0, T is not P(=O)(OM)—; and when Q or T is $S(O_2)$ —, m and n are not 0;

Z represents a functional group that enables linkage of the hydrophilic linker to a cytotoxic drug via a disulfide, thioether, thioester, hydrazone, ether, ester, carbamate, carbonate, secondary, tertiary, or quaternary amine, imine, cycloheteroalkane, heteroaromatic, alkoxime or amide bond;

R₁, R₂, R₃, and R₄, are the same or different and are absent, linear alkyl having from 1-6 carbon atoms, branched or cyclic alkyl having from 3 to 6 carbon atoms, linear, branched or cyclic alkenyl or alkynyl, or ester, ether or amide having 2-6 carbon atoms, or polyethyleneoxy unit of formula (OCH₂CH₂)_p, wherein p is an integer from 1 to about 1000, or combination thereof, provided that when Q and T are each independently —S(O₂)—or —S(O)—, R₂ is absent, linear alkyl having from 1-6 carbon atoms, branched alkyl having from 3 to 6 carbon atoms, linear or branched alkenyl or alkynyl, or ester, ether or amide having 2-6 carbon atoms, or polyethyleneoxy unit of formula (OCH₂CH₂)_p, wherein p is an integer from 1 to about 1000, or combination thereof,

or R_1 , R_2 , R_3 and R_4 are respectively a chain of two or more atoms selected from the group consisting of C, N, O, S, Si, and P that covalently connects a cell-surface binding ligand, a phosphinate or sulfonyl group, a conjugated drug and among themselves (R_1 , R_2 , R_3 , and R_4), provided that when Q and T are each

independently — $S(O_2)$ — or —S(O)—, R_2 is a straight or branched chain of two or more atoms selected from the group consisting of C, N, O, S, Si, and P that covalently connects a cell-surface binding ligand, a phosphinate or sulfonyl group, a conjugated drug, R_1 , R_3 or R_4 ;

R₅ and R₆, are the same or different and are absent, H, linear alkyl having from 1-6 carbon atoms, branched or cyclic alkyl having from 3 to 6 carbon atoms, linear, branched or cyclic alkenyl or alkynyl, or ester, ether or amide having 2-6 carbon atoms, or polyethyleneoxy unit of formula (OCH₂CH₂)_p, wherein p is an integer from 1 to about 1000, or combination thereof;

M is H, or Na, or K, or N+ $R_1R_2R_3$ or a pharmaceutical salt. Ex. 1002, 1:22–2:13.

Claims 3, 20, 24, 26, 29, and 30 are also independent claims.

C. Prosecution History

Pertinent to the issues discussed herein, in an Office Action dated March 8, 2018, the Examiner rejected claim 1 under pre-AIA 35 U.S.C. § 102(b) as anticipated by Lees.² Ex. 1018, 42. The Examiner stated:

Lees discloses a heterobifunctional linker which is an Nhydroxysuccinimide vinylsulfone (page 22, formula at bottom of page) having substituted or unsubstituted alkyl chain of 1 to 20 (page 23, top formula) or including carbon atoms polyethylglycol (page 23, middle formula). Lees discloses the use of the linker to attach a derivatized polysaccharide to one end and a protein to the other (page 23, lines 17-19). The NHS vinylsulfone or Lees anticipates instant formula 55 shown in Figure 6 of the instant specification. Therefore the NHS portion represents a functional group that enables reaction of the linker with a cell binding agent, and the vinyl group enables linkage of the linker to a cytotoxic drug as indicated by structure 56 of Figure 6.

¹ The claims at issue are set forth in Exhibit 1002, to the extent they have modified the claims in Exhibit 1001.

² Lees, WO 97/41897, pub. Nov. 13, 1997 (Ex. 2026).

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Id. at 42–43.

In an amendment dated March 20, 2018, the Applicant amended claim 1 to add "and when Q or T is — $S(O_2)$ —, m and n are not 0."

Ex. 1018, 45–46. As part of the same amendment, Petitioner added that R_1 – R_6 may be absent:

R₁, R₂, R₃, and R₄, are the same or different and are <u>absent</u>, linear alkyl having from 1-6 carbon atoms, branched or cyclic alkyl having from 3 to 6 carbon atoms, linear, branched or cyclic alkenyl or alkynyl, or ester, ether or amide having 2-6 carbon atoms, or polyethyleneoxy unit of formula (OCH₂CH₂)_p, wherein p is an integer from 1 to about 1000, or combination thereof,

or R_1 , R_2 , R_3 and R_4 are respectively a chain of two or more atoms selected from the group consisting of C, N, O, S, Si, and P that covalently connects a cell-surface binding ligand, a phosphinate or sulfonyl group, a conjugated drug and among themselves (R_1 , R_2 , R_3 , and R_4);

R₅ and R₆, are the same or different and are <u>absent</u>, H, linear alkyl having from 1-6 carbon atoms, branched or cyclic alkyl having from 3 to 6 carbon atoms, linear, branched or cyclic alkenyl or alkynyl, or ester, ether or amide having 2-6 carbon atoms, or polyethyleneoxy unit of formula (OCH₂CH₂)_p, wherein p is an integer from 1 to about 1000, or combination thereof;

Id.

In remarks accompanying the amendment, the Applicant stated that "[s]upport for these amendments can be found throughout the Specification, particularly, the Examples (see, e.g., Examples 69, 75, 86, 116, 122, 128, 135, 138, 142 and 147)." Ex. 1018, 59.

In a response to the rejection over Lees, also accompanying the amendment, the Applicant stated as follows:

Lees discloses protein/polysaccharide conjugates prepared via a heterobifunctional vinylsulfone, such as an N-hydroxysuccinimide vinylsulfone having the following structure:

This compound corresponds to

$$Y-R_1+Q-R_2+T-R_3+R_4-Z$$
(I)

recited in claim 1 of the present application, where Y is

Q (or T) is
$$-S(O_2)$$
-, m (or n) is 1, n (or m) is 0, $R_2(R_3)$ and R_4 - R_6 are absent, and Z is

On the other hand, claim 1 of the present application recites that when Q (or T) is $-S(O_2)$ -, m and n are not 0, thereby excluding the above noted compound described in Lees.

Id. at 62.

Subsequent to issuance on November 20, 2018, the '682 patent was the subject of an ex parte reexamination, resulting in claim amendments (and some new claims) in a certificate of reexamination. *See* Ex. 1001, code (45), Ex. 1002.

D. Decision on Institution

In a section discussing claim construction, the prior Decision finds that it was undisputed that moieties Y or Z enable connection of the linker to a cell-binding agent (Y) or a cytotoxic drug (Z). Dec. 18. The prior Decision also finds that it was undisputed that Q and T are defined as one of three chemical compounds: sulfone, sulfonide³, or phosphinate. *See id*. The

³ It appears that the prior Decision intended to refer to sulfoxide instead of sulfonide. *See* Dec. 19.

prior Decision states that the central issue for claim interpretation is whether Y or Z must act independently, or whether they can act in concert, with an adjoined Q or T compound. *Id.*⁴ Ultimately, the prior Decision holds that "Y and Z must independently enable their respective chemical reactions because Patent Owner (as Applicant) disclaimed embodiments in which Y or Z was adjoined to a sulfone compound with no *additional* adjacent sulfone, sulfoxide or phosphinate, in order to distinguish Lees." *Id.* at 19.

In apparent agreement with the cited Patent Owner Preliminary Response, the prior Decision states that "Patent Owner's language accompanying its claim amendments makes clear that the amendments were meant to overcome Lees' disclosure of a terminal vinyl sulfone group as the group that 'enables linkage of the hydrophilic linker to a cytotoxic drug."

Id. at 22–23 (citing Prelim. Resp. 24–25; Personalized Media Cmmc'ns, LLC v. Apple Inc., 952 F.3d 1336, 1340 (Fed. Cir. 2020)). The prior Decision concludes that the Applicant disclaimed embodiments in which Y or Z was adjoined to a sulfone compound with no additional adjacent sulfone, sulfoxide or phosphinate, in order to distinguish Lees." Id. at 19 (citing Ex. 1018, 42–43 (Examiner's rejection), 62 (Applicant's amendment and comments) (emphasis in panel decision)).

The prior Decision states:

In light of the amendment made to exclude the compound described in Lees, we are not persuaded by Petitioner's argument that Y or Z of claim 1 could be interpreted to comprise a vinyl group adjacent to a sulfone without additional Q and T groups, as required by the phrase "when Q or T is —S(O2)—, m and n are not 0." Patent Owner's amendment disclaimed compounds in

⁴ This decision ultimately does not answer this broader question, but instead focuses only on a narrower subset of that question: whether vinyl sulfone can be mapped to Y-Q/Z-T. *See infra*.

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which the terminal group is vinyl sulfone without one or more adjacent Q and T groups.

Id. at 23 (citing, e.g., Ex. 1018, 45, 62).

The prior Decision concludes: "We therefore interpret claim 1 to exclude compounds in which the sole terminal group is vinyl sulfone without one or more adjacent Q and T groups." *Id.* at 24. The prior Decision also concludes, purportedly for this reason, that "claim 1 does not read on embodiments 55, 75, 99, 119, and 138 because Applicant relinquished such subject matter during prosecution to obtain allowance." *Id.* In terms of the central claim interpretation issue, the prior Decision concludes that Y and Z must independently enable their respective reactions, without assistance from an adjoining Q or T. *Id.* at 25.

II. ANALYSIS

A. Legal Standards

The Director delegated review to this panel to "determine whether the record demonstrates that the Decision misapprehended or overlooked any issue raised in the Director Review request." *See* Paper 19, 2 (citing www.uspto.gov/patents/ptab/decisions/delegated-rehearing-panel §§ 2.C–D; 37 C.F.R. § 42.71(d)."). "[T]he DRP shall determine whether the record, including any request for Director Review, demonstrates that the original Board decision misapprehended or overlooked any issue that was previously addressed in papers filed with the Board."

www.uspto.gov/patents/ptab/decisions/delegated-rehearing-panel § 2.D.

We construe each claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). Under this standard, claim terms are generally given their plain

and ordinary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313–14 (Fed. Cir. 2005) (*en banc*).

"[I]n order for prosecution disclaimer to attach, the disavowal must be both clear and unmistakable." *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1325 (Fed. Cir. 2013). "[T]he doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003).

B. Claim Construction

Petitioner argues that is impossible to interpret the claim amendment relied on in the prior Decision as disclaiming vinylsulfone from serving as the Q-Y or T-Z combinations. Paper 18, 9. Petitioner argues that, had the Applicant intended to disavow vinylsulfone from serving as Q-Y or T-Z, the proffered amendment would not have been necessary at all. *Id*.

Patent Owner argues, *inter alia*, that "[a]n applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well." Paper 22, 6 (citing *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1374 (Fed. Cir. 2007)).

Claim 1 recites that "Y represents a functional group that enables reaction of the hydrophilic linker with a cell-binding agent." Ex. 1002, 1:31–32. Claim 1 further recites that "Z represents a functional group that enables linkage of the hydrophilic linker to a cytotoxic drug...." *Id.* at 1:40–41.

The prior Decision sets forth an analysis as to whether Y or Z must act independently of Q or T (to enable binding to a cell-binding agent or drug). See Decision 18. In answering this question, the prior Decision looks to whether the Patent Owner (as the Applicant) made a disclaimer during prosecution in filing an amendment to overcome the Lees reference. See id. at 21–25.

We determine that the dispositive issue is, when the hydrophilic linker contains a vinylsulfone group, whether one of Y and Z may be understood to be a vinyl group with one of Q and T as a sulfone group (i.e., the vinyl group and the sulfone group are mapped to separate letters), or instead whether one of Y and Z must be a vinylsulfone group (i.e., the vinyl group and the sulfone group are mapped to the same letter). At the same time, we consider whether there is a prosecution history disclaimer and what, if any, is the scope of the disclaimer.

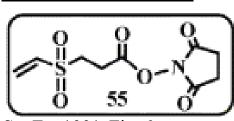
The prior Decision finds that there was a prosecution history disclaimer. The prior Decision provides two distinct versions of this disclaimer.

The prior Decision provides a first version of the disclaimer: "Patent Owner (as Applicant) disclaimed embodiments in which Y or Z was adjoined to a sulfone compound with no additional adjacent sulfone, sulfoxide or phosphinate, in order to distinguish Lees." Decision 19. We agree with this finding. It is clear that the Applicant disclaimed compound 55⁵ of the Specification in order to overcome the anticipation rejection over

⁵ Compound 55 is reproduced below:

Lees (where the Examiner found that the species in Lees was the same as compound 55). See Ex. 1018, 42–43 (amendment), 62 (response to rejection) ("claim 1 of the present application recites that when Q (or T) is - S(O₂)-, m and n are not 0, thereby excluding the above noted compound described in Lees"). In doing so, we agree with the original Board panel's implicit finding that the disclaimer is essentially equal in scope to the amendment that the Applicant filed along with the Applicant's response to the rejection over Lees. The amendment provides, in part, "when Q or T is —S(O₂)—, m and n are not 0." Ex. 1018, 45–46. The statement of the disclaimer on page 19 of the Decision is a restatement of the amendment, e.g., if Q is a sulfone, then there must be at least one T, where T is a sulfone, sulfoxide or phosphinate. See Ex. 1002, 1:33–34, 1:38–39 (claim 1) (claim 1 claim provides that Q or T can be a sulfone, sulfoxide or phosphinate; if m and n are not 0, then there is at least one Q and at least one T).

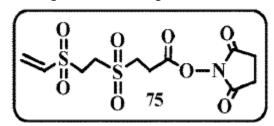
Later, the prior Decision provides a second version of the disclaimer: "We therefore interpret claim 1 to exclude compounds in which the sole terminal group is vinyl sulfone without one or more adjacent Q and T groups." Decision 24 (emphasis added); see also id. at 23 ("Patent Owner's amendment disclaimed compounds in which the terminal group is vinyl sulfone without one or more adjacent Q and T groups"). We understand that, in this version of the disclaimer, both a Q and a T group are required, in addition to a vinylsulfone group. In other words, under this second version



See Ex. 1001, Fig. 6.

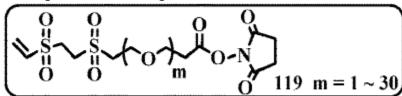
of the disclaimer, claim 1 would not be satisfied by a molecule with two sulfone groups (and no other functional groups drawn from the group of sulfone, sulfoxide, and phosphinate) because, according to the prior Decision, there would need to be two sulfone groups in addition to the vinylsulfone group. Our understanding of the second version of the disclaimer, as not being satisfied by two sulfone groups, is consistent with the statement in the prior Decision immediately following this second version of the disclaimer: "With this understanding, we agree with Petitioner that claim 1 does not read on embodiments 55, 75, 99, 119, and 138 because Applicant relinquished such subject matter during prosecution to obtain allowance." Decision 24. Compounds 75⁶ and 119⁷ each have two sulfone groups, and compound 138⁸ has one sulfone group and one phosphinate

⁶ Compound 75 is reproduced below:



See Ex. 1001, Fig. 7.

⁷ Compound 119 is reproduced below:



See Ex. 1001, Fig. 9.

⁸ Compound 138 is reproduced below:

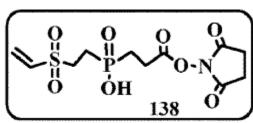
group. Thus, it appears that, under the second version of the disclaimer, two sulfone groups would not fall within the scope of the claim.

In view of the additional briefing, we are persuaded that the second version of the disclaimer is erroneous, as it misapprehends or overlooks the following portions of the prosecution history.

First, the predicate for the Applicant's filing of a claim amendment was that the Applicant itself was mapping Z as vinyl and Q (or T) as sulfone in compound 55 (and the species in Lees which was the basis for the anticipation rejection). The Examiner stated that: "Lees anticipates instant formula 55 shown in Figure 6 of the instant specification." Ex. 1018, 42–43.

We agree with Petitioner that the Examiner understood Z to be vinyl when the Examiner stated "the vinyl group enables linkage of the linker to a cytotoxic drug" (Ex. 1018, 42–43) because the claim recites "Z represents a functional group that enables linkage of the hydrophilic linker to a cytotoxic drug...." Ex. 1002, 1:40–41.

The Applicant then explicitly provided a mapping of the claim where Z is vinyl and Q or T is sulfone. See Ex. 1018, 62. Patent Owner asserts that the Applicant was merely repeating—not adopting or otherwise agreeing with—the Examiner's mapping of the claim. Paper 22, 2, 10. We disagree with Patent Owner's assertion, because the Applicant does not state that it was merely repeating the Examiner's mapping of Lees; nor does the



See Ex. 1001, Fig. 10.

Applicant express disagreement with the Examiner's characterization of Lees. Further, the Applicant provided much more detail than the Examiner did in characterizing Lees. Whereas the Examiner did not explicitly state that vinyl was Z, the Applicant provides a detailed mapping of Lees as follows:

This compound corresponds to

$$Y-R_1+Q-R_2 = T-R_3 = R_4-Z$$

$$R_5 = R_6$$
(I)

recited in claim 1 of the present application, where Y is

Q (or T) is
$$-S(O_2)$$
-, m (or n) is 1, n (or m) is 0, $R_2(R_3)$ and R_4 - R_6 are absent, and Z is

Ex. 1018, 62. Thus, contrary to Patent Owner, when the above portions of the record are considered as a whole, we find that the Applicant was stating the Applicant's own mapping of the compound in Lees.

Further, the Applicant could not have intended to map Z as vinylsulfone for two reasons. First, if Z were vinylsulfone in Lees, then there would be no Q (or T) as sulfone and indeed no Q (or T) at all, which would not satisfy the condition of the amendment for m and n to be non-zero (i.e., having at least one Q and at least one T), which is that Q (or T) is sulfone. See Ex. 1018, 45.

Second, there would not have been a need for the Applicant to file an amendment if Z were vinylsulfone, because the Applicant would have been able to distinguish claim 1 from the species in Lees on another basis, i.e., by pointing out that Q and T cannot be 0 at the same time, i.e., based on a pre-

existing claim limitation. See Ex. 1018, 45 ("m and n are integer from 0 to 5, but not 0 at the same time:").

Moreover, the Applicant explicitly relied on compounds 75 and 138 as support for the claim amendment. This buttresses the understanding that compounds 75 and 138 fall within the scope of claim 1, and were not disclaimed. Patent Owner relies on Uship Intellectual Props., LLC v. United States, 714 F.3d 1311, 1316 (Fed. Cir. 2013), for the proposition that prosecution history disclaimer can result in a disclosed embodiment not being covered by the claims. See Paper 22, 8–9. Patent Owner also argues that compounds 75 and 138 were relied on to support the part of the claim amendment that provided that R_1 – R_6 may be absent. See Paper 22, 3. However, the Applicant's Remarks merely stated that "Support for these amendments can be found throughout the Specification, particularly, the Examples (see, e.g., Examples 69, 75, 86, 116, 122, 128, 135, 138, 142 and 147)." Ex. 1018, 59. The Applicant did not distinguish different parts of the amendment in the statement of support, which indicates that these examples were intended the support the amendment as a whole, including that "and when Q or T is $-S(O_2)$ —, m and n are not 0." See Ex. 1018, 45. Therefore, in our view, the Applicant was relying on compounds 75 and 138 as support for the entirety of the amendment.

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⁹ At a later time, during reexamination, with respect to a different rejection, Patent Owner stated that "[t]he Examiner appeared to miss a portion of the proposed structure" before Patent Owner provides a mapping of Y as vinyl. See Ex. 1019, 72. For this rejection as well, Patent Owner here argues that Patent Owner was in reexamination repeating the Examiner's mapping of the claim. See Paper 22, 3. We do not reach that issue. As it pertains to claim 1, for the disclaimer that distinguishes Lees, we determine that the mapping represents Patent Owner's views as well as those of the Examiner.

In view of the foregoing, and consistent with the Examiner's and the Applicant's mapping at the time of the claim amendment, when the hydrophilic linker contains a vinylsulfone group, we determine that the vinyl group should be mapped to Y or Z, and the sulfone group should be mapped to Q or T. We determine that such mapping satisfies the "enables reaction" and "enables linkage" requirements of claim 1.

III. CONCLUSION

We conclude, on the present record, that the Applicant made a clear and unmistakable prosecution history disclaimer, which was essentially commensurate in scope with the March 20, 2018 claim amendment. We conclude that the amendment to claim 1 was predicated on an understanding, by both the Examiner and the Applicant, that, when there is a terminal vinylsulfone, Y (or Z) is mapped to vinyl, and Q (or T) is mapped to sulfone, such that there must be at least one additional phosphinate, sulfonyl, or sulfoxide group as Q (or T).

We do not reach Petitioner's arguments as to claim 3. On remand, the prior Decision's findings as to claim 3 may need to be reconsidered in view of the revised construction of claim 1.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that rehearing is granted;

FURTHER ORDERED that the claim construction is modified;

FURTHER ORDERED that the Decision (Paper 17) is vacated;

and

FURTHER ORDERED that the case is remanded to the panel for further proceedings consistent with this opinion.

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