

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SYNAFFIX B.V.,
Petitioner

v.

HANGZHOU DAC BIOTECH CO., LTD.,
Patent Owner

IPR2022-01531
Patent No 10,131,682

**PATENT OWNER'S RESPONSE TO
PETITIONER'S REQUEST FOR DIRECTOR REVIEW**

I. INTRODUCTION

The Institution Denial should be affirmed. This is Petitioner's *fourth* chance at claim construction. Petitioner filed its Petition, a Reply to the POPR, and a supplemental brief accusing Patent Owner ("DAC") of making "material misrepresentation/misleading arguments" in support of the challenged claim construction. The Board rightfully rejected each one. Now Petitioner accuses the Board of misapprehending chemistry/formulas and abusing its discretion by ruling in DAC's favor on claim construction. The Board, however, did no such thing.

As explained further below, Petitioner's Director Review request is premised on a mischaracterization of what the Board actually held. Petitioner argues that the Board held that DAC disclaimed "vinyl sulfones from serving as the Q-Y or T-Z groups in claim 1." Paper 18 at 9. It did not. Instead, the Board more narrowly held that DAC "disclaimed compounds in which the terminal group is vinyl sulfone *without one or more adjacent Q and T groups.*" Paper 17 at 23. In other words, DAC "disclaimed embodiments in which Y or Z was adjoined to a sulfone compound with no *additional adjacent* sulfone [SO₂], sulfoxide or phosphinate." *Id.* at 19 (emphasis added). Sulfone, sulfoxide, or phosphinate are the Q and T groups.

The Board's ruling is consistent with: (1) DAC's distinguishing of the Lees reference during the '682 Patent's original prosecution; and (2) DAC's unambiguous disavowal of prior-art compounds that "contain[ed] only one SO₂" during the

'682 Patent's reexamination. And as the Board correctly found, its ruling is also consistent with the '682 Patent's Specification and all extrinsic evidence before the Board. Paper 17 at 24-25. Petitioner's review request should be denied.

II. '682 PATENT FILE HISTORY

The Patent Office issued three Office Actions during prosecution of the '682 Patent. POPR at 24. In the second non-Final Office Action, the Examiner rejected Claim 1 under pre-AIA 35 U.S.C. § 102(b) as being anticipated by Lees' heterobifunctional linker, called a "N-hydroxysuccinimide (NHS) vinyl sulfone." *Id.* at 25-26; EX1018 at 42; EX2025 at 7-8. According to the Examiner, "[t]he NHS vinylsulfone [of] Lees anticipates instant formula 55." EX1018 at 42. The Office Action stated, "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." *Id.* at 42-43.

DAC responded by amending Claim 1, adding "when Q or T is -S(O)₂-, m and n are not 0." *Id.* at 45. In its remarks about Lees, DAC repeated (but did not adopt) the Examiner's mapping of vinyl as Z and explained that, in the Examiner's mapping of Lees, Q or T is SO₂, "m (or n) is 1, n (or m) is 0," and R₂-R₆ is absent. *Id.* at 62; Paper 14 at 6. DAC then distinguished amended Claim 1, stating "[o]n 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 in Lees." EX1018 at 62.

Thus, DAC excluded compounds having a terminal vinyl sulfone without an additional adjacent Q or T group, such as another sulfone.

DAC also amended Claims 1-4, adding that R₁-R₆ may be “absent.” (*id.* at 45-49). DAC stated that “[s]upport for these amendments can be found throughout the Specification” and pointed to various compounds, including compounds 75 and 138, which support the R₁-R₆ may be “absent” amendment. *Id.* at 59.

During reexamination of the '682 Patent, the Examiner rejected Claim 3 under pre-AIA 35 U.S.C. § 102(b) as being anticipated by and/or rendered obvious under pre-AIA 35 U.S.C. § 103 over Govindan. EX1019 at 12; Paper 14 at 6-7. DAC restated the rejection to clarify that “[t]he Examiner appeared to miss a portion in the proposed structure. It is presumed the following structure was intended.” EX1019 at 72; Paper 14 at 6-7. DAC then repeated the Examiner’s mapping of sulfone as Q (EX1019 at 13-15) and vinyl as Y, and distinguished Claim 3 based on R₂, which excluded Govindan’s structure (*id.* at 72; Paper 14 at 6-7). DAC also unambiguously distinguished prior-art compounds that “contain[ed] only one SO₂.” EX1019 at 78, 80.

III. LEGAL STANDARD

“[A] claim in a patent as allowed must be read and interpreted with reference to claims that have been cancelled or rejected, and the claims allowed cannot by construction be read to cover what was thus eliminated from the patent.” *Schriber*–

Schroth Co. v. Cleveland Trust Co., 311 U.S. 211 (1940). “[P]rosecution history disclaimer narrows the meaning of the claim consistent with the scope of the claim surrendered.” *Biogen Idec, Inc. v. GlaxoSmithKline*, 713 F.3d 1090, 1095 (Fed. Cir. 2013).

IV. ARGUMENT

Petitioner contends that the Board misapprehended the claimed chemical formulas, certain compounds in the Specification, and the file history of the ’682 Patent¹ in finding a prosecution disclaimer. Paper 18 at 1. Petitioner further contends the Board abused its discretion by purportedly finding disclaimer “*sua sponte*.” *Id.* at 14-15. Petitioner is incorrect. As explained below, DAC disclaimed certain scope associated with claim 1 and the Board correctly relied upon this disclaimer, which it noted was briefed by *both parties* (Paper 17 at 23), without abuse of its discretion.

A. DAC’s Disclaimer During Prosecution and Affirmation of Disclaimer During Reexamination.

Petitioner argues DAC’s claim amendment and remarks in response to the Examiner’s rejection over Lees did not amount to disclaimer. Paper 18 at 8-9. Petitioner’s view is both unsupported and contradicted by Federal Circuit precedent.

¹ Petitioner asserts the European counterpart of the ’682 Patent has been revoked. Paper 18 at 2. But that decision has been suspended as it is on appeal. *See* Article 106(1) EPC. Further, the Federal Circuit instructs against relying on foreign decisions due to differing laws and procedures. *AIA Eng’g Ltd. v. Magotteaux Int’l S/A*, 657 F.3d 1264, 1279 (Fed. Cir. 2011).

When DAC amended Claim 1 to overcome Lees (which is *identical to Compound 55*) and provided supporting arguments, DAC necessarily disclaimed a portion of the scope of Claim 1. Prosecution disclaimer includes “amendments to the claims and arguments made to convince the examiner.” *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985); *see also Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1266 (Fed. Cir. 2012) (patentee’s statements during reexamination can be considered “in keeping with the doctrine of prosecution disclaimer”).

In no uncertain terms, DAC’s amendment adding “when Q or T is -S(O)₂-, m and n are not 0” and remarks excluding Lees’ compound in which the terminal group is vinyl sulfone without at least one *additional* sulfone, resulted in disclaimer. *See* Section II *supra*. Accordingly, specific embodiments originally disclosed in the Specification (*e.g.*, compounds 55 (identical to Lees), 75, 99, 119, and 138) were excluded from the scope of Claim 1. Paper 17 at 24; *see North Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1346 (Fed. Cir. 2005) (“the fact that claims do not cover certain embodiments disclosed in the patent is compelled when narrowing amendments are made in order to gain allowance over prior art”).

Petitioner claims it is “impossible” to interpret DAC’s amendment to overcome Lees as a disclaimer because “had the Applicant intended to disavow vinyl sulfone from serving as Q-Y or T-Z, the preferred amendment would not have been necessary at all.” Paper 18 at 9. Only Petitioner characterizes one of DAC’s

amendments as “preferred.” Moreover, the Federal Circuit has made clear 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.” *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1374 (Fed. Cir. 2007). That applies here.

And in case there were any doubt, during reexamination of the ’682 Patent, DAC unambiguously affirmed its disclaimer of compounds in which the terminal group is vinyl sulfone without one or more additional adjacent Q and T groups, such as another sulfone. DAC argued Claim 30 (which has a similar Q/T/*m/n* limitation as Claim 1) overcame the asserted reference because the prior-art compound “contain[ed] *only one* SO₂” and did not correspond to Claim 30 where, like Claim 1, both *m* and *n* must be present. EX1019 at 80 (emphasis added).

B. The Board Correctly Interpreted The Claimed Structures And Prosecution History.

Notwithstanding the foregoing, Petitioner mischaracterizes the Board’s holding in its fourth attempt to argue claim construction.

Petitioner alleges that the Board found DAC disclaimed “vinyl sulfones from serving as the Q-Y or T-Z groups in claim 1.” Paper 18 at 9. Petitioner then accuses the Board of a “a glaring misapprehension of the underlying chemistry and/or claimed chemical formulas.” Paper 18 at 8. But the Board did not find disclaimer of

the broad subject matter, as Petitioner claims. Instead, the Board more narrowly found that “Patent Owner’s amendment disclaimed compounds in which the terminal group is vinyl sulfone without one or more adjacent Q and T groups.” Paper 17 at 23; *see also* Section IV.A *supra*. The Board showed that it understood the underlying chemistry and formulas, specifying that DAC “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” (emphasis added). *Id.* at 19. The Board explained it was further “persuaded by the testimony of Patent Owner’s declarant regarding the understanding of one of ordinary skill in the art of the meaning of the claim terms and context of their use.” *Id.* at 25. The Board then concluded that this disclaimer along with other lines of intrinsic and extrinsic evidence supported DAC’s proposed construction. Paper 17 at 24-25.

Notwithstanding Petitioner’s mischaracterization of the disclaimer, Petitioner incorrectly argues the Board’s finding is at odds with certain vinyl sulfone-containing compounds in the Specification.² Paper 18 at 11-12. As an initial matter,

² Petitioner contends the Board’s claim construction excludes “every single example in the patent” containing vinyl sulfone. Paper 18 at 1-2. Not so. The Board’s constructions are consistent with compounds containing a terminal vinyl sulfone and one or more Q and T groups and also cover many other structures disclosed in the Examples with different combinations of chemical substituents serving as Y, Z, Q, and T. *See, e.g., id.* at Figs. 1-19. Moreover, Petitioner improperly reads the structures shown in various example reactions to limit claim scope despite the specific non-limiting language used in the Specification (“[T]he following

Petitioner ignores that the Board extensively considered these formulas, including Petitioner's supplemental briefings on these structures. Paper 17 at 16-17, 20-21, 24. Petitioner now states the Board is wrong despite conceding that "claims can sometimes be interpreted to omit disclosed embodiments." Paper 18 at 11.

Petitioner's argument focuses on DAC's purported "express identification" of compounds 75 and 138 to support its claim amendment (Paper 18 at 6, 11-12) as negating disavowal of claim scope. Again, Petitioner mischaracterizes the record. DAC did not identify compounds 75 and 138 in support of its Q/T/m/n amendment to Claim 1. EX1018 at 59. As explained in Section II, Petitioner made multiple claim amendments, including to allow R₁-R₆ to be absent in each of then-pending Claims 1-4 (*id.* at 45-49). Petitioner then collectively remarked that "support may be found throughout the Specification," cited various compounds, and confirmed that no new matter was added (*id.* at 59). As with the other cited structures, compounds 75 and 138 support at least one of the R₁-R₆ substituents being absent. Thus, the compounds do not contradict DAC's remarks to make clear that the amendments were meant to overcome Lees' disclosure of a terminal vinyl sulfone without one or more additional adjacent Q and T groups. See *Uship Intellectual Props., LLC v. U.S.*, 714 F.3d 1311, 1316 (Fed. Cir. 2013) ("Even if the specification had disclosed an

examples" are "not intended to limit the scope of the invention.") EX1001 at 36:36-38.

embodiment [directed to the disputed limitation], prosecution disclaimer could result in that embodiment not being covered by the claims.”)

Petitioner also argues the Board’s “faulty interpretation of Q/T and Y/Z” affected its analysis of Claim 3 and further accuses the Board of “unsupported fact-finding when it conclude[d] that a sulfone becomes complexed to HRP through a vinyl-sulfone mediated reaction, making a derivatized protein.” *Id.* at 13. As described above, however, the Board’s interpretations of Q/T/Y/Z are consistent with the intrinsic and extrinsic record. *See supra* Section IV.B. Petitioner fails to point to any authority that limits the Board’s authority or precludes the Board from reconciling multiple lines of evidence as it did with Claim 3. POPR at 48; Ex. 1005 at 4046; Ex. 2001 at ¶57. In fact, the Board’s conclusion regarding Claim 3 conveys its understanding of the placement and reactivity of functional groups, including Q.

C. The Board Did Not Abuse Its Discretion.

Petitioner lastly contends that the Board abused its discretion. Paper 18 at 14-15. Petitioner’s reasoning is fundamentally flawed in multiple ways.

First, Petitioner argues that the Board acted “*sua sponte*” to find prosecution history disclaimer. Paper 18 at 12-13. This is incorrect; the Board noted that both parties addressed this issue during briefing. Paper 17 at 23. But even if the Board’s finding was “*sua sponte*,” Petitioner has not identified any case law precluding the Board’s authority to find disclaimer.

Second, Petitioner argues that the Decision “is clearly unreasonable, with no record evidence supporting the Decision’s finding of disclaimer.” Paper 18 at 9. The Board’s interpretation of DAC’s claim amendment and remarks is reasonable, however, and consistent with an unequivocal disclaimer. *See* Sections II, IV.A-IV.B.

Third, Petitioner contends that a prosecution history disclaimer finding contradicts statements made during patent prosecution of Claim 1 or reexamination of Claim 3, where DAC allegedly identified a vinyl group as both Z and Y and vinyl sulfone as the combination of TZ and QY. Paper 18 at 9-11; Ex. 1018 at 36–43; Ex. 1019 at 72. As acknowledged by the Board, however, in both cases DAC repeated the Examiner’s proposed identifications prior to arguing against them rather than advocating for those designations. *See* Section II, Paper 14 at 6–7; Paper 17 at 17.

The prosecution history disclaimer, in combination with the other intrinsic and extrinsic evidence, contributed to the Board’s interpretations of Y, Z, Q, and T. Paper 17 at 24-25. The Board concluded that “Y and Z must independently enable their respective chemical reactions.” *Id.* at 19. Thus, Petitioner’s identified vinyl sulfone-containing compounds, including those “functionally identical to compound 75” (Paper 18 at 15), were properly excluded from the scope of Claims 1 and 3.

V. CONCLUSION

For the aforementioned reasons, DAC respectfully submits that Petitioner’s review request should be denied, and the Institution Denial should be affirmed.

Date: December 15, 2023

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document was served in its entirety on December 15, 2023 upon the following parties via Electronic Mail:

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