

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

Patent No. 10,131,682

Ex Parte Reexamination Certificate Issued: January 4, 2021

Title: HYDROPHILIC LINKERS AND THEIR USES FOR CONJUGATION OF
DRUGS TO A CELL BINDING MOLECULES

Inter Partes Review No. IPR2022-01531

**PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO
EXCLUDE**

Petitioner hereby respectfully submits its opposition to Patent Owner DAC's Motion to Exclude (Paper 50, "Motion"), which advances only improper and/or meritless arguments.

I. INTRODUCTION

A Motion to Exclude is not a proper vehicle to argue miscellaneous disputed issues, assert that evidence should be accorded little weight, or complain that alleged new evidence or argument should be stricken. Despite this, DAC does so for most of its Motion. DAC's improper arguments should be disregarded. The remaining arguments fail to show why any challenged evidence is inadmissible. Petitioner respectfully requests that the Motion be denied.

II. ARGUMENT

A. DAC's Complaints about Timing, Scope, and Prior Art Status Are Improper for a Motion To Exclude.

The November 2019 Consolidated Trial Practice Guide ("CTPG") provides "[a] motion to exclude *is not* a vehicle for . . . address[ing] arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply." CTPG, 79 (emphasis added). DAC's complaint that "Petitioner untimely and improperly filed new Exhibits 1089 and 1090 with Petitioner's Sur-Sur-Reply" (Motion, 1) is improper argument about the timing and scope of sur-sur-reply evidence. DAC cites 37 C.F.R. §42.23(b); CTPG, 73-74; and the April 4, 2025, Order, which relate to the scope of reply papers and do not address admissibility.

1. A Motion to Exclude Evidence is Limited to Admissibility Objections

“A motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay).” CTPG, 79. DAC’s complaints about timing and scope make no attempt at explaining why those issues make Exhibits 1089 and 1090 inadmissible from an evidentiary perspective. Mot., §II.A. DAC’s only relevant objections to be considered go to relevance and prejudice, which are discussed separately below (*infra*, §II.B-C).

2. DAC’s Challenges Are Not Proper for a Motion to Exclude

The CTPG also provides “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a motion to strike.” CTPG, 80; *see also Streck, Inc. v. Ravgen, Inc.*, IPR2021-01577, Paper 62, 91 (P.T.A.B. Apr. 18, 2023) (denying a motion to exclude, *inter alia*, when the argument should have been raised in a motion to strike); *Apple Inc. v. Parus Holdings, Inc.*, IPR2020-00686, Paper 37, 41-42 (P.T.A.B. Sept. 9, 2021) (same). DAC cites two cases that did grant a motion to exclude exhibits first introduced in expert deposition and submitted with a sur-reply. Mot., 2. However, the Board in one of these cases expressly authorized the argument to be made outside a motion to strike. *Intel Corp. v. ParkerVision, Inc.*,

IPR2020-01265, Paper 44, 66 (P.T.A.B. Jan. 21, 2022) (“As set forth in our Order, we authorized . . . in lieu of a motion to strike, Petitioner to file a chart including the page and line numbers for each portion of Patent Owner’s Sur-reply that Petitioner contends exceeds the proper scope for a sur-reply.”). Such authorization was not obtained here.

Accordingly, DAC’s motion to exclude Exhibits 1089 and 1090 on any non-FRE-based objection is improper and should be rejected for that reason alone.

3. The Deposition Exhibits Should Not be Excluded

The April 4, 2025, Order set the scope of evidence to be submitted with Petitioner’s Sur-Sur-Reply, stating that “Petitioner may not introduce new evidence other than the deposition transcript of Patent Owner’s declarant.” Paper 40, 4. Petitioner did not run afoul of the Order because Exhibits 1089 and 1090 were a legitimate part of the deposition transcript, and were submitted accordingly.¹

Notably, the undersigned counsel has been previously involved in an almost identical situation, where the petitioner (represented by the undersigned) was likewise authorized to file a sur-sur-reply on a new claim construction issue raised

¹ If it would be the Board’s preference, the deposition transcript could be resubmitted with the two documents attached as exhibits to the transcript, rather than as separate exhibits in the P-TACTS filing system.

during the proceeding. *Life Spine, Inc. v. Globus Medical, Inc.*, IPR2022-01434, Paper 31, 6 (P.T.A.B. Oct. 12, 2023). Specifically, petitioner was authorized by the Board to take the deposition of the patent owner's sur-reply expert, and then to file the transcript with its sur-sur-reply brief. *Id.*

While the Board's order in that case similarly stated that the sur-sur-reply "may not be accompanied by new evidence other than the deposition transcript of the cross examination of the sur-reply declarant" (*id.*), during the conference call that preceded the Order, the parties expressly discussed with the Board whether documents introduced during the deposition to cross-examine or impeach the witness should be submitted. On the call, the panel answered in the affirmative reasoning that such exhibits were properly a part of the deposition transcript, with the only caveat being that any such exhibits must have been legitimately introduced for cross-examination/impeachment purposes.

Subsequently, petitioner filed its sur-sur-reply brief (*id.*, Paper 43) accompanied by the deposition transcript (*id.*, Ex. 1091) and the exhibits introduced during the deposition (*id.*, Exs. 1085-1090). The panel properly allowed those exhibits to be filed into the record because they were a part of the transcript, without which the transcript would be incomplete.

Here, the Board's April 4, 2025, Order likewise authorized Petitioner to cross-examine DAC's sur-reply declarant, Dr. Tumey. Paper 40, 3. During that

cross-examination, Dr. Tumey was asked about a specific reaction scheme shown in Figure 15 of the '682 patent at issue in this proceeding—a reaction scheme that Petitioner believes supports its position in this proceeding regarding what the claim term “enables reaction” encompasses. Rather than admit what was clearly taught in Figure 15, Dr. Tumey took the remarkable position that the reaction scheme in Figure 15 contained some kind of error, speculating that “there may have been some sort of a copy-and-paste error” in the patent. Ex. 1091, 22:8-9.

Given this testimony during cross-examination (which, under the circumstances, was Petitioner’s last chance to elicit testimony on this topic), Petitioner legitimately impeached Dr. Tumey’s testimony by introducing an exhibit that directly refuted his live testimony and questioned him about its teachings. Patent Owner could have elicited re-direct testimony from Dr. Tumey on this exhibit, but chose not to do so. Ex. 1091, 37:6-38:3.

Similarly, Dr. Tumey was asked whether he knew of catalysts for reacting hydroxylamine-functional groups to form an oxime linkage. *Id.*, 31:18-22. Apparently in strict adherence to his position that such reactions must occur “independently” (i.e., without the assistance of any catalysts) (Ex. 2047, ¶¶21-22), he testified that he was not aware of any such catalysts. Consequently, Petitioner introduced Exhibit 1090 to show that in fact other catalysts (besides the acid indicated in Exhibit 1089) were known in the art for this reaction. In his testimony,

Dr. Tumey was either taking a litigation-inspired position, or does not have the chemical expertise in this area that he purports to have. Exhibit 1090 was thus another legitimately introduced document during Dr. Tumey's deposition used to impeach the witness in response to live testimony given. These facts distinguish the situation here from the exhibits that were excluded in DAC's cited *Netflix* case. *Netflix, Inc. v. DivX, LLC*, IPR2020-00511, Paper 46, (P.T.A.B. Aug. 13, 2021) (excluding exhibits that were allegedly shown to the witness "in a clear attempt at circumventing the PTAB's prohibition against new sur-reply evidence and arguments").

Patent Owner apparently takes the position that **no documents** could be introduced during Dr. Tumey's deposition given the procedural posture. This makes no sense. The Board expressly authorized Petitioner to cross-examine Dr. Tumey; if Petitioner were forced to merely accept whatever answers Dr. Tumey gives without any ability to counter ill-informed or speculative testimony about alleged errors in the patent-at-issue, then it would not be a cross-examination at all. No party could zealously cross-examine a witness without the ability to timely confront the witness with impeaching evidence.

Further, Exhibits 1089 and 1090 are deposition exhibits to the second deposition of DAC's expert, Dr. Tumey. This deposition of Dr. Tumey is cited extensively by Petitioner in the Sur-Sur-Reply, and the exhibits to this deposition

are necessary to provide a complete record. *Intex Recreation Corp. v. Team Worldwide Corp.*, IPR2018-00872, Paper 133, 64-65 (P.T.A.B. Sept. 11, 2019) (finding it proper to maintain deposition exhibits “in the record, as they are relevant to testimony in the deposition[], even if that testimony is not ultimately relied upon by Patent Owner or Petitioner[] in this proceeding”).

4. Petitioner did not Present any New Arguments in its Sur-Sur-Reply

DAC argues that Petitioner presented a new argument that claim term “Y” should not “be a functional group that independently enables reaction with a cell-binding agent.” Mot., 3. However, as noted above, if DAC’s concern was “new arguments” about the claim term “Y,” “the way to raise is a motion to strike, not a motion to exclude.” *Streck*, IPR2021-01577, Paper 62, 91; *see also Vibrant Media, Inc. v. General Elec. Co.*, IPR2013-00170, Paper 56, 31 (P.T.A.B. June 26, 2014) (“A motion to exclude is not a mechanism to argue that a reply [or sur-sur-reply] contains new arguments.”).

In any event, Petitioner did not present a “new argument.” The challenged exhibits show that Dr. Tumey was incorrect or less than forthcoming when he claimed that Y group hydroxylamines must react “independently” (*see* Paper 43, 4), and that he is not knowledgeable on this topic in stating that he could not think of other catalysts besides acids could catalyze this reaction (*id.*, 5). Thus, the Sur-Sur-Reply does not contain “new arguments” against patentability that rely on the

challenged exhibits. Rather the Sur-Sur-Reply supports Petitioner's contention from the outset of this proceeding that Y groups "enable reaction" even when "assisted" by other conditions or substituents, such as, *inter alia*, adjacent sulfone groups, catalysts, heat, light, etc. The deposition and impeachment of Dr. Tumey's testimony via the challenged exhibits support those Sur-Sur-Reply arguments, and show why DAC's Sur-Reply arguments to the contrary are incorrect.

5. Challenging Prior Art Status is Improper for a Motion to Exclude

DAC argues "Exhibit 1090 is not prior art, and it should be excluded from the Board's patentability analysis for that reason alone." Mot., 4. However, a motion to exclude is not the proper vehicle for objections challenging the prior art status of Ex. 1090. *Beable Education, Inc. v. Achieve3000, Inc.*, IPR2021-01169, Paper 34, 89 (P.T.A.B. Jan. 3, 2023) ("[A] motion to exclude is not the proper mechanism to challenge the prior art or printed publication status of an exhibit."). DAC's argument concerns a "substantive issue that goes to the sufficiency of the evidence, not to admissibility at issue here." *Arista Networks, Inc. v. Cisco Sys., Inc.*, IPR2016-00303, Paper 53, 9 (P.T.A.B. May 25, 2017).

Further, as noted above (*supra*, §II.A.3-4), Petitioner relies on Ex. 1090 to impeach Dr. Tumey. *See also* Paper 43, 1-2 (impeaching Dr. Tumey's assertion that cleavage is an unexpected side reaction). Exhibit 1090 need not be prior art to

the '682 patent to show that Dr. Tumey is not the credible expert DAC claims him to be.

Furthermore, the way in which these exhibits impeach Dr. Tumey's testimony also makes their prior art status irrelevant. One issue in this case is whether it is improper to for Patent Owner to import a limitation into the claims requiring that the terms "enables reaction" and/or "enables linkage" for Y and Z must further do so "independently." Exhibits 1089 and 1090 are relevant precisely because they undermine Dr. Tumey's position that Y groups—such as hydroxylamine groups—must "independently" enable reaction. The exhibits do not need to qualify as prior art to speak to that factual issue and show that Dr. Tumey is mistaken in apparently suggesting that Y functional groups, like hydroxylamines, are capable of "independently" reacting in the absence of catalysts (e.g., acids or other catalysts), heat, etc.

Lastly, to the extent DAC alleges that Petitioner cited portions of Ex. 1090 not discussed during the deposition of Dr. Tumey (Mot., 4-5), those portions were only cited to provide context (Ex. 1090, ¶[00102]) or confirm direct testimony (Ex. 1090, ¶[00136]), and not substantively relied upon in the Sur-Sur-Reply. *See* Paper 43, 2, 5.

B. DAC's Relevance Objections Are Unfounded.

DAC argues that “Exhibits 1089 and 1090 and related deposition testimony should be excluded because they are not relevant.” Mot., 4. However, “[a]n objection to the admissibility of deposition evidence must be made during the deposition.” 37 C.F.R. §42.64(a). Furthermore, “[a] motion to exclude evidence should: (a) Identify where in the record the objection originally was made.” CTPG, 79.

DAC did not, and could not, identify in its Motion where in the record a relevance objection was made, because the record contains no such objection. While DAC objected to additional exhibits if the Board did not previously allow them (Ex. 1091, 28:1-7), this is an objection to scope, not admissibility. *See* 37 C.F.R. §42.64(b)(1) (“The objection must identify the grounds for the objection with sufficient particularity.”); *Streck*, IPR2021-01577, Paper 62, 91 (rejecting the argument that an objection to new evidence could be relied on for any other purpose).

Further, nowhere does its Motion cite FRE 401, again showing a lack of sufficient particularity. These reasons alone should be fatal to DAC's relevance objections. But even if these objections are considered on their merits, the objections should not be sustained.

Evidence is relevant if “it has *any tendency* to make a fact more or less probable than it would be without the evidence” and it is of consequence in the action. Fed. R. Evid. 401 (emphasis added). This is a “very low threshold.” *Google Inc. v. Performance Price Holdings, LLC*, CBM2016-00049, Paper 37, 35 (P.T.A.B. Sept. 13, 2017). The challenged evidence clearly meets the low threshold for relevance under FRE 401, given that it directly contradicts Dr. Tumey’s live testimony or impeaches his credibility and his level of expertise. Certainly Dr. Tumey’s credibility is of consequence in this action, and the evidence in question speaks directly to that issue. Exhibits 1089 and 1090 thus meet the low threshold needed for being relevant to various aspects of the disputes between the parties and should not be excluded.

C. DAC’s Objections Under FRE 403 Are Meritless as The Board Can Balance Prejudice Concerns Without Excluding Evidence.

Finally, DAC cites FRE 403 and argues that “any purported relevance would be substantially outweighed by the unfair prejudice.” Mot., 6. The only prejudice DAC identifies is the inability to address these exhibits in further briefing. *Id.*, 2, 6. However, as noted previously, DAC took a break after the cross-examination concluded, spoke with Dr. Tumey in private, and had the opportunity to elicit redirect testimony from Dr. Tumey, yet chose not to do so. *Supra*, §II.A.3.

Moreover, when “the decision is by an administrative agency, rather than a jury, there is a diminished concern that such exhibits would be prejudicial.” *Eli*

Lilly and Co. v. Teva Pharmaceuticals International GmbH, IPR2018-01422, Paper 80, 162 (P.T.A.B. Feb. 18, 2020); *see also Gulf States Utilities Co. v. Ecodyne Corp.*, 635 F.2d 517, 519 (5th Cir. 1981) (“Excluding relevant evidence in a bench trial . . . on the basis of ‘unfair prejudice’ is a useless procedure.”). There is no merit in excluding this evidence as the Board is adequately equipped to balance this diminished prejudice concern. *Proppant Express Investments, LLC v. Oren Technologies, LLC*, IPR2018-00914, Paper 38, 19 (P.T.A.B. Mar. 13, 2019) (precedential) (“[T]he Board can carefully balance the interest in preventing harassment against fairness and prejudice concerns.”).

III. CONCLUSION

For the above reasons, the challenged evidence should remain in the record for the Board to consider as it deems appropriate. *Corning Incorporated v. DSM IP Assets B.V.*, IPR2013-00053, Paper 66, 19 (P.T.A.B. May 1, 2014) (“If the record on review contains not only all evidence which was clearly admissible, but also all evidence of doubtful admissibility, the court which is called upon to review the case can usually make an end of it, whereas if evidence was excluded which that court regards as having been admissible, a new trial or rehearing cannot be avoided.”). Accordingly, Petitioner respectfully requests that the Board deny the Motion.

Dated: May 23, 2025

Respectfully submitted,

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CERTIFICATE OF LENGTH (37 C.F. R. §42.24)

The undersigned hereby certifies that the foregoing document has twelve (12) pages and thus complies with the applicable page limit.

Dated: May 23, 2025

By: /Michael R. Houston
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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing
PETITIONER’S OPPOSITION TO PATENT OWNER’S MOTION TO
EXCLUDE is being served on counsel for Patent Owner by filing through the
Board’s electronic filing system (P-TACTS), and by electronic mail this 23rd day
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