

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EMBODY, INC. AND ZIMMER BIOMET HOLDINGS, INC.,
Petitioners,

v.

LIFENET HEALTH,
Patent Owner.

Case IPR2025-00249
U.S. Patent No. 11,318,227 B2

**PETITIONERS' REQUEST FOR REHEARING OF THE FINAL WRITTEN
DECISION AS TO CLAIMS 2 AND 3**

Filed on behalf of Petitioners

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.71(d), Petitioners respectfully request rehearing of the limited portion of the Final Written Decision (Paper 41, “Final Decision” or “Final Dec.”), determining that Petitioners failed to establish the unpatentability of dependent claims 2 and 3 of U.S. Patent No. 11,318,227 (“the ’227 patent”).

Rehearing is warranted because the Final Decision concerning dependent claims 2 and 3 rests on a material misapprehension of the record: the Final Decision states that Petitioners never argued that Kuo’s rolled scaffold remains within the scope of the “sheet” limitations of claims 2 and 3, when Petitioners expressly made that argument and Patent Owner expressly disputed it.

For claim 2, the Final Decision states that “Petitioner fails to argue” that claim 2’s “one or more elongated sheets” encompass Kuo’s rolled structure and that Petitioners offered no claim-construction argument supporting that position. (Final Dec. 43.) But Petitioners expressly argued that “[b]ecause claim 2 uses the open-ended transition ‘comprising,’ Kuo’s additional rolling step does not remove it from the claim’s scope. *A rolled sheet is still a sheet.*” (Pet. Reply 21–22 (citing Ex. 1001, 8:40–43, 23:39–40, claim 1; Ex. 1210 ¶¶ 65–66.) (emphasis added).) Petitioners supported that position with the ’227 patent’s intrinsic evidence, which itself describes “folding or rolling the sheet” and depicts elongated sheets, including multiple layers of sheets, being folded or rolled to form an implant. (Pet.

Reply 21–22 citing Ex. 1001, 8:40–43 (discussing Figs. 9A–9C).) Thus, Petitioners explained how the claim language and specification show that claim 2 should be construed to cover a rolled sheet.

Patent Owner understood and directly disputed that argument, contending in its Sur-reply that rolling causes the scaffold to cease being in sheet form when implanted. (Sur-reply 24–25 (citing Pet. Reply 21).) Thus, the parties squarely presented and litigated the precise issue the Final Decision said Petitioners had not raised.

That misapprehension is material. The Board correctly found (and Petitioners do not challenge) that the Huang2/Kuo combination renders obvious claim 1, including the use of Huang2’s flat scaffold followed by Kuo’s rolling process. (Final Dec. 31–41.) The issue for claims 2 and 3 therefore was not whether the combination includes a sheet that is rolled; the Board’s own correct findings establish that it does. The issue was whether rolling the sheet takes the resulting structure outside the dependent claims’ “sheet” limitations. Petitioners argued that it does not; Patent Owner argued that it does. The Final Decision

should have resolved that dispute on the merits, rather than sustaining claims 2 and 3 based on the erroneous premise that Petitioners had not presented the argument.¹

The same error applies to claim 3. Petitioners expressly argued that Kuo's multiple rolled sheets render obvious claim 3's "multiple layers of one or more sheets," because intrinsic evidence, as well as Dr. Simpson's testimony, shows that claim 3 covers rolled sheets. (Pet. Reply 21–22 (citing Ex. 1001, 8:40–43).) The '227 patent itself confirms that an elongated roll may be formed from "sheet or sheets." (Ex. 1001, 8:40–43 (discussing Figs. 9A–9C).)

Rehearing therefore requires no new evidence, reference, or obviousness combination. It requires only that the Board consider the argument the parties actually presented and disputed and decide claims 2 and 3 on the existing record. Petitioners respectfully request rehearing by the Board to consider these points.

II. LEGAL STANDARD

Under 37 C.F.R. § 42.71(d), a party may request rehearing by specifically identifying the matters the Board misapprehended or overlooked and identifying

¹ At institution, the Board found that Petitioner "sufficiently demonstrated" Kuo's disclosure satisfies claims 2 and 3. (Dec. 34.) The Final Decision, however, does not explain why that showing became inadequate, instead faulting Petitioner for failing to make an argument that was expressly presented. (Final Dec. 42–43).

where each matter was previously addressed. The Board has granted rehearing where, as here, its final decision rested on a misapprehension of an argument actually presented by the petitioner.

For example, in *WesternGeco LLC v. PGS Geophysical AS*, IPR2015-00313, Paper 45 at 3–4 (PTAB Feb. 3, 2017), the Board granted rehearing of a Final Written Decision after concluding that it had “misapprehended Petitioner’s arguments” concerning a dependent claim and modified the Final Written Decision to hold that previously sustained claim unpatentable. *See also Handi Quilter, Inc. v. Bernina International AG*, IPR2014-00270, Paper 17 at 23-24 (PTAB Dec. 30, 2014) (granting rehearing after concluding that the Board had “misapprehended the significance” of an argument presented in the Petition).

The same principle applies here. Petitioners do not ask the Board to entertain a new argument or reconsider an argument it considered and rejected. Petitioners ask the Board to correct the stated premise that Petitioners failed to make an argument that the record demonstrates Petitioners expressly made and Patent Owner expressly disputed.

III. THE BOARD MISAPPREHENDED PETITIONERS’ EXPRESS ARGUMENT THAT KUO’S ROLLED SHEET SATISFIES CLAIM 2

Claim 2 recites: “The method of claim 1, wherein the scaffold is in the form of one or more elongated sheets.” (Ex. 1001, 23:38–39.)

The Final Decision recognized that Petitioners relied on Huang2 and Kuo in asserting the obviousness of dependent claim 2. The Final Decision also acknowledged Petitioners’ argument that Huang2’s electrospun fibers “would constitute a sheet” and that Kuo expressly refers to “scaffold sheets.” (Final Dec. 42–43 (citing Pet. 41; Ex. 1018 ¶¶ 7, 20, 22).) The Final Decision further explained that Petitioners’ proposed modification involves first obtaining the flat scaffold sheet disclosed in Huang2—the first step of Kuo’s process—and then rolling that sheet, as in the third step of Kuo’s process. (Final Dec. 38–39 (citing Ex. 1018, Fig. 1).) On that basis, the Board determined that claim 1 is not patentable. (*Id.* at 42.)

That finding is significant for claim 2 and, by extension, claim 3. The Final Decision itself establishes that the asserted combination includes a *flat scaffold sheet that is subsequently rolled*. (Final Dec. 39.) Thus, the dispute for claims 2 and 3 was not whether the proposed combination includes a sheet or whether that sheet is subsequently rolled. According to the Board’s own findings, it does.

Nevertheless, the Final Decision concluded that Petitioners “fail[] to argue” that the “one or more elongated sheets” recited in claim 2 would encompass the rolled structure and that Petitioners did not articulate a claim-construction argument supporting that position. (Final Dec. 43.) That conclusion overlooks Petitioners’ express argument.

A. Petitioners expressly argued that Kuo’s rolling step does not remove the sheet from the scope of claim 2

In responding to the Petition, Patent Owner argued that while Huang2 disclosed a “sheet,” Kuo disclosed “a spirally rolled structure” that was, according to Patent Owner, fundamentally different from a “sheet,” and thus a POSA would not have been motivated to combine Huang2 and Kuo. (PO Resp. 39–40; Sur-reply 20–21.) Patent Owner relied on expert testimony, dictionary definitions, and Dr. Simpson’s deposition testimony in support of that distinction. (*Id.* at 40.)

Petitioners directly answered that contention in their Reply. Petitioners explained that, contrary to Patent Owner’s assertion, Kuo’s process begins “with a flat ‘scaffold sheet.’” (Pet. Reply 15–16.) Petitioners further explained that the third step of Kuo’s process is to roll that sheet. (*Id.* at 17.) The Board ultimately adopted that understanding of Kuo in finding motivation to combine. (Final Dec. 38–40.)

Petitioners then expressly addressed the effect of that rolling step on claim 2: “Because claim 2 uses the open-ended transition ‘comprising,’ Kuo’s additional rolling step does not remove it from the claim’s scope. *A rolled sheet is still a sheet.*” (Pet. Reply 21–22 (emphasis added).) And, as discussed further below, Petitioners identified specific intrinsic evidence to support their construction.

Thus, Petitioners expressly made the precise argument the Final Decision states was missing. The argument was not merely that Kuo begins with a sheet.

Petitioners expressly addressed the legal significance of Kuo’s subsequent rolling step and explained why that additional step does not take the resulting structure outside claim 2.

Patent Owner indisputably understood Petitioners’ argument. In its Sur-reply, Patent Owner argued that dependent claim 2 dictates the form of the scaffold recited in claim 1 and that “[t]he ‘comprising’ transitional phrase does not alter the express claim requirements regarding form.” (Sur-reply 24.) Patent Owner further stated: “Contrary to Petitioner’s argument, rolling a scaffold dictates that, when implanted, it is no longer in the form of one or more sheets.” (*Id.* at 24–25 (citing Pet. Reply 21).) In support of its argument, Patent Owner relied on Figure 1 of Kuo to differentiate a prepared scaffold and a rolled scaffold. (*Id.* at 25 (citing Ex. 1018, Fig. 1).)

Patent Owner therefore recognized and disputed Petitioners’ position that a rolled sheet remains within the scope of claim 2. Both parties understood and litigated the same issue: Petitioners argued that Kuo begins with a sheet and that rolling that sheet does not remove it from the claim; Patent Owner argued that, once rolled, the scaffold is no longer “in the form of” a sheet when implanted.

The Final Decision should have resolved that substantive dispute. Instead, it resolved claim 2 on the premise that Petitioners had failed to present their position. That premise is incorrect.

B. Petitioners supported their argument with the '227 patent's intrinsic evidence

Petitioners' argument was not merely the unsupported assertion that "a rolled sheet is still a sheet." Petitioners expressly relied on the '227 patent itself. The Reply explained that the patent discusses "folding or rolling the sheet." (Pet. Reply 21–22 (citing Ex. 1001, 8:40–43).)

The cited intrinsic evidence is clear on this point. The written description expressly states that "the biocompatible matrix is *prepared by folding or rolling the sheet or sheets*, along with the direction of nanofiber alignment to form an *elongated roll implant*." (Ex. 1001, 8:40–43 (emphasis added).) This portion of the written description discusses Figures 9A–9C, which depict multiple layers of elongated sheets—being folded or rolled to form the implant. (*Id.* at Figs. 9A–9C, 2:13–19.)

This intrinsic evidence thus directly supports Petitioners' argument as it shows that the '227 patent itself describes the *sheet or sheets as being rolled to form the elongated roll implant*. It therefore confirms that a sheet and a rolled configuration are not mutually exclusive concepts.

Dr. Simpson likewise addressed the precise issue. (Pet. Reply (citing Ex. 1219 ¶¶ 65–67).) In the cited portions of his declaration (Ex. 1219 ¶¶ 65–67), he explained that Kuo's preferred embodiment begins with a flat "sheet," that cells are placed and grown on that flat sheet, and that the sheet is rolled later in Kuo's

process. (Ex. 1219 ¶ 65 (citing Ex. 1018, Fig. 1, claim 1; Ex. 1220, 160:5–15, 161:12–162:14).) More importantly, Dr. Simpson expressly disagreed with the proposition that a rolled sheet is no longer a sheet, explaining that “a POSA would understand that a rolled sheet is a sheet.” (Ex. 1219 ¶ 65.) He supported that opinion by reference to the ’227 patent’s disclosure that the sheet may be folded or rolled. (*Id.* (citing Ex. 1001, 8:40–43).)

Additionally, in his declaration in support of institution (Ex. 1003 ¶¶ 60), Dr. Simpson noted that “FIGS 9A, 9B, and 9C depict exemplary scaffold prepared into an elongated roll by folding an elongated sheet (9A), an elongated roll by rolling an elongated sheet (9B), and a composite of multiple layers of elongated sheets (9C). (*Id.*, 2:13-19.).” (*Id.* ¶ 60)

Accordingly, Petitioners’ Reply identified both intrinsic and expert support for the very claim-scope argument that the Final Decision states Petitioners failed to make. Rehearing should consider that existing evidence rather than dispose of claim 2 based on the erroneous premise that no such argument was presented.

C. Kuo confirms that the proposed combination begins with the claimed sheet and then rolls it

The Final Decision itself recognized Kuo’s disclosure that “the sheet is spirally wound in a jelly-roll-like manner” (Ex. 1018 ¶ 7), “contacting a scaffold sheet . . . and rolling the scaffold sheet” (*Id.* ¶ 20), and contacting a scaffold sheet,

rolling it into “a spirally wound tissue construct,” and implanting it (*Id.* ¶ 22).
(Final Dec. 43.)

These disclosures support Petitioners’ argument. Kuo does not begin with a roll and substitute that roll for a sheet. It expressly begins with a *scaffold sheet* and then rolls the scaffold sheet. Thus, the relevant question is whether the subsequent rolling step takes that sheet outside the scope of claim 2. Petitioners expressly argued that it does not, including because claim 2 uses the open-ended transition “comprising.” (Pet. Reply 21–22.) The Board therefore should reconsider claim 2 on the argument actually presented and determine that Huang2/Kuo renders claim 2 obvious.

IV. THE SAME MISAPPREHENSION AFFECTED CLAIM 3, WHICH PETITIONERS SEPARATELY ADDRESSED

Claim 3 recites: “The method of claim 1, wherein the scaffold is a composite of multiple layers of one or more sheets.” (Ex. 1001, 23:40–41.)

The Final Decision concluded that claim 3 suffered from “the same problem” as claim 2 and again stated that Petitioners had not advanced a claim-construction argument supporting the challenge. (Final Dec. 43–44.) But Petitioners expressly addressed claim 3 and its additional “multiple layers” limitation.

A. Petitioners expressly argued that Kuo’s multiple rolled sheets render claim 3 obvious

Petitioners’ Reply expressly stated: “A rolled sheet is still a sheet, and Kuo’s use of multiple rolled sheets renders claim 2—and claim 3’s ‘multiple layers of one or more sheets’—obvious.” (Pet. Reply 21 (citing Ex. 1219 ¶¶ 65–66).)

Thus, Petitioners did not merely rely on their claim 2 argument by implication. They expressly applied that argument to claim 3 and separately identified Kuo’s use of multiple rolled sheets as rendering obvious claim 3’s “multiple layers of one or more sheets” limitation.

Petitioners further supported that argument with Kuo’s disclosure that a scaffold may be in the form of “sheets” and with evidence concerning multilayer sheets. (Pet. Reply 22 (citing Ex. 1018 ¶ 24; Ex. 1219 ¶¶ 65, 67; Ex. 1220, 146:14–22, 148:20–150:12; Exs. 1206, 1209).)

Dr. Simpson likewise separately addressed claim 3. He testified that Kuo teaches “sheets” as a scaffold shape and using several rolled sheets to form a macroscopic tissue construct. (Ex. 1219 ¶ 66 (citing Ex. 1018 ¶¶ 24, 29).) He further responded to Dr. Mikos’s contention that there would have been no motivation to use multiple sheets, explaining that multiple layers were known to provide enhanced mechanical properties relevant to tendon and ligament scaffolds. (*Id.* ¶ 67 (citing Ex. 1220, 146:14–22, 148:20–150:12; Exs. 1206, 1209).)

Thus, Petitioners presented both the sheet/rolling argument and a separate evidentiary basis for the “multiple layers” limitation of claim 3.

B. The ’227 patent expressly confirms that multiple layers of sheets can be rolled into an implant

The cited intrinsic evidence is particularly relevant to claim 3. (Pet. Reply 21–22 (citing Ex. 1001, 8:40–43).) The written description states that the “sheet or sheets” may be folded or rolled to form an elongated roll implant. (Ex. 1001, 8:40–43.) The cited portion of the written description discusses Figures 9A–9C, which depict a scaffold prepared into an elongated roll from a composite of multiple layers of elongated sheets. (Ex. 1001, Figs. 9A–9C.)

The ’227 patent therefore expressly discloses the very relationship at issue in claim 3: *multiple layers of sheets being rolled to form an elongated roll implant*. That disclosure further supports Petitioners’ position that the claimed “multiple layers of one or more sheets” is not excluded merely because the layers are subsequently rolled. Again, Petitioners relied on this intrinsic record, and the Board did not address it because it concluded that Petitioners had failed to present the underlying argument.

C. Patent Owner’s response confirms that claim 3 was actually argued

Patent Owner disputed Petitioners’ claim 3 showing, arguing that Kuo’s use of plural “sheets” did not itself disclose a composite of multiple layers and that

Petitioners had not adequately explained how or why a multilayer sheet would be employed in Kuo's rolled scaffold. (PO Resp. 41–42.)

That response confirms that Petitioners' claim 3 theory was before the Board. The parties disputed whether Kuo's teachings concerning sheets and multiple sheets rendered obvious the claimed "multiple layers of one or more sheets." The Final Decision should therefore have addressed that dispute on the merits rather than conclude that Petitioners had failed to present a supporting argument.

Accordingly, rehearing is warranted as to claim 3 for the same fundamental reason as claim 2: the Final Decision's stated basis rests on a material misapprehension of arguments Petitioners expressly presented and supported.

V. REHEARING REQUIRES NO NEW EVIDENCE OR THEORY

The requested rehearing consideration to be corrected is discrete and narrow. Petitioners do not seek to introduce a new reference, new evidence, or a new obviousness combination. Petitioners also do not challenge the Board's determination that claim 1 is obvious over Huang² and Kuo.

Rehearing requires only that the Board consider the arguments Petitioners actually presented concerning claims 2 and 3. The Final Decision did not consider Petitioners' argument that Kuo begins with a scaffold sheet; that Kuo subsequently rolls that sheet; that claim 2's open-ended "comprising" language means the

additional rolling step does not remove the sheet from the claim’s scope; that “[a] rolled sheet is still a sheet”; and that Kuo’s use of multiple rolled sheets renders claim 3’s “multiple layers of one or more sheets” obvious. (Pet. Reply 21–22.) The Final Decision’s conclusion that Petitioners failed to make those arguments is therefore a material misapprehension of the record. Because that perceived omission supplied the stated basis for sustaining claims 2 and 3, correcting the error requires rehearing of those claims on the existing record.

VI. REQUESTED RELIEF

For the foregoing reasons, Petitioners respectfully request that the Board grant rehearing of the Final Written Decision as to claims 2 and 3.

Upon rehearing, Petitioners respectfully request that the Board reconsider claims 2 and 3 based on the arguments and evidence actually presented in the Petition and Reply—including Petitioners’ express argument that “[a] rolled sheet is still a sheet,” the argument that Kuo’s subsequent rolling step does not remove the sheet from claim 2’s scope, and the argument that Kuo’s use of multiple rolled sheets renders obvious claim 3’s “multiple layers of one or more sheets” limitation.

On that existing record, Petitioners respectfully request that the Board modify the Final Written Decision to determine that claims 2 and 3, like claim 1 from which they depend, are unpatentable as obvious over Huang² and Kuo.

Respectfully submitted,

Dated: September 2, 2026

By: /Howard W. Levine/
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CERTIFICATE OF SERVICE

I hereby certify that on September 2, 2026, I caused a true and correct copy of the foregoing **Petitioners' Request for Rehearing of the Final Written Decision as to Claims 2 and 3** to be served via electronic means upon the Patent Owner's counsel of record at the following addresses:

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