

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARTHREX, INC.
Petitioner

v.

MEDSHAPE, INC.,
Patent Owner

IPR2025-00053

Patent No. 7,985,222

OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND
MANUFACTURE

PATENT OWNER'S PRELIMINARY SUR-REPLY

TABLE OF CONTENTS

	Page(s)
I. The Plain Language of the Claim Requires an Order of Steps, Which Patent Owner Argued to the District Court	1
A. At the District Court, Patent Owner Argued Stretching Does Not Occur Until After Insertion	2
B. The Intrinsic Record Confirms Claim 1 Requires Inserting Before Stretching.....	4
II. Institution Should Be Denied Under Section 325(d).....	6
III. Institution Should Be Denied Under the <i>Fintiv</i> Factors	7

The plain language of claim 1 requires an order of steps as Patent Owner detailed to the District Court. Critically, Petitioner recognizes Ground 1 fails under the correct interpretation of claim 1, as it never urges Monassevitch discloses the required order of steps. Petitioner's other arguments against discretionary denial (1) rely on outdated authority, including that the PTAB no longer considers average time to trial statistics, and (2) fail to address the actual case schedule in which dispositive motions are due long before the statutory deadline for a final written decision. Institution should be denied.

I. The Plain Language of the Claim Requires an Order of Steps, Which Patent Owner Argued to the District Court

The plain language of the claims recites an express order of steps, as indicated by the antecedent basis. Claim 1 requires "inserting a bone device ... into a first bone fragment and a second bone fragment." Element 1.3 relies on this statement for antecedent basis when it recites "creating in a responsive portion of *the bone device* at least a partial transformation into a stress-induced martensitic phase *via stretching*." Through antecedent basis, the stretching occurs after insertion into at least one of the two bone fragments. The Federal Circuit has explained, a claim "requires an ordering of steps when the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires" an order of steps. *TALtech Ltd. v. Esquel Apparel, Inc.*, 279 F. App'x 974, 978 (Fed. Cir. 2008). This is the case here.

A. At the District Court, Patent Owner Argued Stretching Does Not Occur Until After Insertion

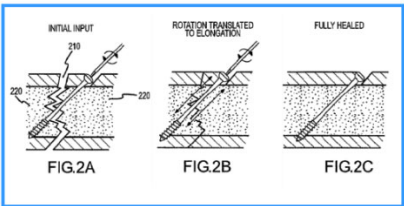
The stretching recited by claim 1 does not occur until after the bone device is inserted into at least one piece of bone. Paper 6 at 2-3. While Petitioner feigns surprise at this position and asserts “Patent Owner did not advance this proposed construction in the Parallel Litigation” (Paper 8 at 1), Petitioner cites to the Joint Claim Construction Statement (“JCC”) (Ex. 1018) where the parties simply noted disputed terms. As it did there, Patent Owner asserts all terms should receive their plain and ordinary meaning. And as Patent Owner explained at District Court and explains further below, the plain and ordinary meaning of the claim requires insertion before stretching. Petitioner’s “surprise” is disingenuous and inapposite.

In its Responsive claim construction brief, Patent Owner explained “the bone device is *inserted into two pieces of bone*, the responsive portion—the portion of the bone device desired to create compressive force—is linearly stretched in an environment above the austenite finish (“Af”) temperature of the shape memory alloy, and the bone device is then *fixed to a portion of the bone after stretching*; or the bone device is inserted into a first piece of bone *then stretched and inserted into a second bone piece* and then fixed; or the bone device is *inserted into a second piece of bone then stretched and inserted into the first piece of bone* and then fixed.” *Medshape, Inc., et al. v. Arthrex, Inc.*, No. 6:24-cv-151 (W.D. Tex.)

(“Parallel Litigation”), Dkt. 51 at 14.¹ More importantly, Petitioner ***acknowledged and responded to*** this argument in its Reply brief, raising the same intrinsic evidence it raises here. Parallel Litigation, Dkt. 53 at 7 (“Under Enovis’ interpretation, ***the bone device is ‘not stretched’ when inserted.***”).

Petitioner’s intrinsic record-based arguments were also addressed in detail during the *Markman* Hearing with argument and a demonstrative on this point:

The Intrinsic Record Confirms SIM Is Not Present Before the Insertion Process

after inserting the bone device, creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis;	Para. [0037] states “Formation of SIM [stress-induced martensitic] phase within a responsive zone of screw 100, or other osteosynthetic implants and devices, may be achieved prior to surgical placement or as a result of surgical placement.” Para. [0039] states “In one embodiment, the elongation of shank portion 110 occurs during the insertion process into the fractured bone, as depicted in FIG. 2B.” This elongation is indicated by the arrows parallel to the longitudinal axis in Fig. 2B. The depicted stretching/elongation of the shank creates the stress-induced martensitic phase.	
after performing the stretching, fixing the second portion of the bone device to the second bone fragment; and	Para. [0039] states “In one embodiment, the elongation of shank portion 110 occurs during the insertion process, as depicted in FIG. 2B.” Fig. 2B shows stretching/elongation due to turning the screw. Fig. 2C shows the second portion of the bone device (e.g., the threaded end) in the fixed position after the stretching/elongation of the shank has completed.	

(FH Excerpt (Dkt. 48-12), at 11-12; '222 Patent (Dkt. 48-2), Figs. 2A-2C)

13

Parallel Litigation, Dkt. 58 at 13. Patent Owner explained:

[W]hat the record actually shows is that we deleted that first clause but added a subsequent limitation to clarify that, after inserting and stretching, you fix the device to part of the bone. And, as part of this amendment, we clarified that the specification is describing that you’re not stretching anything

¹ These cites are to the docket for the Parallel Litigation. If authorized, Patent Owner will submit each cited document as an exhibit.

before you insert it. You have to -- ***begin the insertion process and then stretch it.***

Parallel Litigation, *Markman* Transcript at 54:3-10. There is no basis for Petitioner's claim that Patent Owner took an inconsistent position at the District Court.

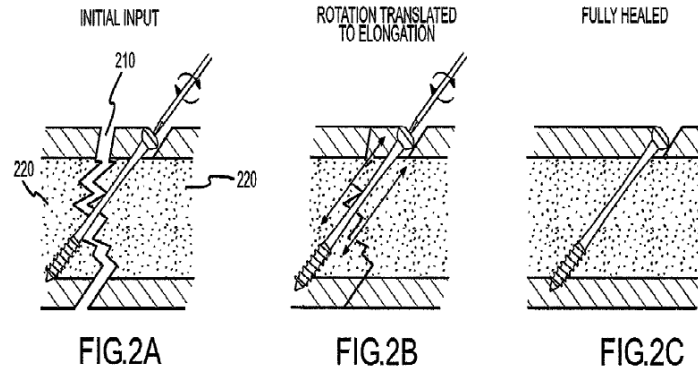
B. The Intrinsic Record Confirms Claim 1 Requires Inserting Before Stretching

Contrary to Petitioner's arguments, the intrinsic record confirms that the claims require an order of steps. *See* Paper 8 at 1-2. Petitioner incorrectly states that the "specification describes stretching occurring before or 'during' the insertion process, but ***not*** 'after' insertion...." *Id.* at 1 (citing Ex. 1001, 6:12-15; 6:49-56; 7:35-41; 5:32-35). Petitioner is wrong. These citations describe stretching may occur during insertion (6:12-15), fixing the device to bone, (6:49-56; 7:35-41), and stretching may occur "prior to surgical placement [i.e., fixing] or as a result of surgical placement" (5:32-35). But in every instance, the device is inserted into at least one of the two bone fragments before stretching.

Next, Petitioner incorrectly suggests Patent Owner's Amendments during prosecution contradict an order of steps. Paper 8 at 2. The record does not show that. During prosecution the Examiner rejected the phrase "after inserting the bone device, creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis." Ex. 1004 at 106-107. In response, applicant

amended the claim to specify, subsequent to the inserting and stretching steps, “fixing” the second portion of the bone device.² *Id.* at 95.

Applicant pointed to Figs. 2A-2C (below) where “bone screw 100 is inserted” and subsequently “rotated to draw the two bone fragments 220 toward one another, creating a compressive force therebetween” (Ex. 1001, 5:45-51), and explained “elongation is indicated by the arrows parallel to the longitudinal axis in Fig. 2B,” “[t]he depicted stretching/elongation of the shank creates the stress-induced martensite,” and “Fig. 2C shows the second portion of the bone device (e.g., the threaded end) in the fixed position after the stretching/elongation of the shank has completed.” Ex. 1004 at 94-95.



Ex. 1001, FIGS. 2A-2C. In adding claims 7 and 8 applicant pointed to this support and expressly stated “in one embodiment, *SIM is not present prior to insert[ion].*”

² “Inserting” and “fixing” should be regarded as different steps. *See, e.g., Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006).

Ex. 1004 at 63 (emphasis added). Thus, applicant was express that the claims require some insertion of the bone device before stretching. *See Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009); *Inverness Med. Switzerland GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1381-82 (Fed. Cir. 2002). Contrary to Petitioner's argument, the prosecution confirms the required order of steps.

II. Institution Should Be Denied Under Section 325(d)

Petitioner's argument begins with the incorrect premise that the Board should decline to exercise discretion because Monassevitch, Hoffman, and Bolesky were not cited during prosecution. Paper 8 at 2. But this is not the rule. *See* 35 U.S.C. § 325(d) (“[T]he Director may take into account whether ... substantially the same prior art or arguments previously were presented to the Office.”).

With respect to Ground 1, Petitioner argues discretionary denial is improper because Campbell was not used to reject claim 50 during prosecution. But the Examiner's use of Campbell during prosecution is irrelevant to the similarities between Monassevitch and Campbell. As explained, both suffer from the same deficiencies with respect to the required order of steps, which Petitioner has tacitly acknowledged by never arguing that Monassevitch discloses the required order of steps. With respect to Ground 2, Petitioner largely urges that Jervis was not substantively addressed because it “was merely listed in an IDS.” Paper 8 at 4. But citation in an IDS sufficiently shows the Examiner considered the reference. *See*

Microsoft Corp. v. Koninklijke Philips N.V., IPR2018-00279, Paper 11 at 12-14 (PTAB June 8, 2018) (finding Office considered a reference where “the Examiner signed an Information Disclosure Statement listing ... [the] reference”). Discretionary denial is appropriate.

III. Institution Should Be Denied Under the *Fintiv* Factors

The USPTO has rescinded its prior memorandum addressing discretionary denial procedures and thus no longer considers “average” time to trial statistics.³ To the extent the Panel accepts these statistics, they cannot outweigh the current case schedule in which dispositive motions are due by September 11, 2025 (Ex. 2001)—nearly eight months before the statutory deadline for a final written decision. It is highly likely trial will occur during those eight months.

With respect to the other factors, Petitioner has not filed a *Sotera*-type stipulation and speculates as to the availability of a stay while ignoring it has not challenged the other asserted patent. Without such a challenge even filed—much less instituted—there is virtually no chance of a stay. Finally, Petitioner’s two grounds are weak. Ground 1 does not address the order of steps and there is no motivation to combine the disparate references addressed in Ground 2. Under these facts the Board should exercise its discretion to deny institution.

³ <https://content.govdelivery.com/accounts/USPTO/bulletins/3d4a99f>.

Dated: March 5, 2025

Respectfully Submitted,

By: /Clay Holloway/

D. Clay Holloway

Reg. No. 58,011

Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Patent Owner's Preliminary Sur-Reply has been served electronically via email upon the following:

MSWoodworth@Venable.com

JJOliver@Venable.com

RCTapparo@Venable.com

Dated: March 5, 2025

By: /Clay Holloway/

D. Clay Holloway

Reg. No. 58,011

Lead Counsel for Patent Owner