

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPINAL ELEMENTS, INC.,
Petitioner,

v.

SPECTRUM SPINE IP HOLDINGS, LLC,
Patent Owner.

PGR2021-00050
Patent 10,709,575 B2

Before ULRIKE W. JENKS, JAMES A. TARTAL, and
JAMES A. WORTH, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision

Determining All Claims Unpatentable

Denying Patent Owner's Revised Contingent Motion to Amend

Dismissing Patent Owner's Motion to Exclude

Denying Petitioner's Motion to Strike

35 U.S.C. §§ 326(d), 328(a); 37 C.F.R. § 42.64(c)

I. INTRODUCTION

Spinal Elements, Inc. (“Petitioner”) filed a Petition requesting a post-grant review of claims 1–9 (“the challenged claims”) of U.S. Patent No. 10,709,575 B2 (Ex. 1001, “the ’575 patent”). Paper 1 (“Pet.”). Spectrum Spine IP Holdings, LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”). Pursuant to 35 U.S.C. § 324, we instituted this proceeding. Paper 8 (“Dec.”).

Patent Owner filed a Patent Owner’s Response (Paper 14, “PO Resp.”), Petitioner filed a Reply to the Patent Owner’s Response (Paper 19, “Reply”), and Patent Owner filed a Sur-reply to the Reply (Paper 23, “Sur-reply”).

Patent Owner filed a Contingent Motion to Amend, seeking to cancel claims 1–9 and propose contingent substitute claims 20–28 if the original claims were found unpatentable. (Paper 15 (“MTA”). After we issued Preliminary Guidance on the MTA (Paper 21), Patent Owner filed a Revised Contingent Motion to Amend, seeking to cancel claims 1–9 and propose revised contingent substitute claims 20–28 if the original claims were found unpatentable. RMTA, App. A. Petitioner filed an Opposition to the RMTA (Paper 32 (“Opp. RMTA”)); Patent Owner filed a Reply to Petitioner’s Opposition to RMTA (Paper 36 (“Reply RMTA”)); and Petitioner filed a Sur-reply to Patent Owner’s Reply to the Opposition to Amend (Paper 41 (“Sur-reply RMTA”)).

Patent Owner also filed a Motion to Exclude (Paper 39 (“MTE”)); Petitioner filed an Opposition to the Motion to Exclude (Paper 40 (“MTE Opp.”)); and Patent Owner filed a Reply to the Opposition to the Motion to Exclude (Paper 42 (“Reply MTE”).

Additionally, Petitioner filed Objections to Patent Owner's submitted evidence (Paper 26); Petitioner filed an Authorized Motion to Strike (Paper 29 ("MTS")); Patent Owner filed an Opposition to Motion to Strike (Paper 30 ("MTS Opp.)); and Petitioner filed a Reply to Patent Owner's Opposition to Motion to Strike (Paper 31 ("Reply MTS")).

An oral argument was held in this proceeding on June 24, 2022, and a transcript was entered into the record. Paper 45 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This Decision is a final written decision under 35 U.S.C. § 328(a) as to the patentability of claims 1–9 of the '575 patent. For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–9 of the '575 patent are unpatentable. We deny Patent Owner's Revised Contingent Motion to Amend as to proposed substitute claims 20–28. We deny Patent Owner's motion to exclude, and deny Petitioner's motion to strike.

A. Related Matters

The parties assert that there are no pending judicial or administrative matters that may affect or be affected by a decision in this proceeding. Pet. 125; Paper 5, 1.

B. The '575 Patent (Ex. 1001)

The '575 patent is titled "Expandable Intervertebral Cage Assemblies." Ex. 1001, code (54). The '575 patent issued from Application No. 16/140,500 ("the '500 application"), filed Sept. 24, 2018. *Id.* at codes (21), (22). The '500 application is a continuation of application No. 15/666,103, filed on Aug. 1, 2017, now Pat. No. 10,111,758, which is a

continuation of application No. 14/878,929, filed on Oct. 8, 2015, now abandoned, which is a continuation-in-part of application No. 14/561,214, filed on Dec. 4, 2014, now Pat. No. 9,585,767, which is a continuation of application No. 13/962,879, filed on Aug. 8, 2013, now Pat. No. 9,585,766. *Id.* at code (63). The '500 application also claims priority to provisional application No. 61/787,744, filed on Mar. 15, 2013, and provisional application No. 61/680,729, filed on Aug. 8, 2012. *Id.* at (60).

The '575 patent relates to an expandable assembly for insertion into an intervertebral space. *See id.* at 1:66–67, 4:24–25. The Specification of the '575 patent describes the assembly as a cage assembly that includes an expander which, when inserted, selectively expands the body of the cage assembly to a desired size. *Id.* at 4:26–29. In one embodiment, cage assembly 1000 includes generally elongate cage body 1010 and expander 1032, as depicted in Figures 1A and 1B, reproduced below.

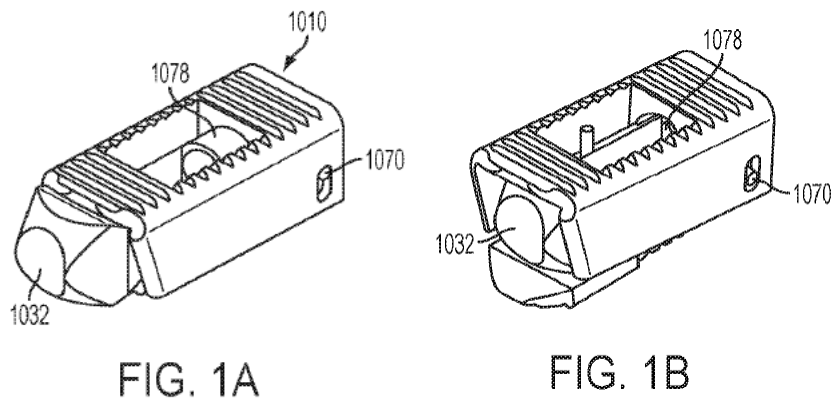


Figure 1A “is a perspective view of an expandable cage for insertion into an intervertebral space in an unexpanded position”, and Figure 1B depicts the expandable cage of Figure 1A in an expanded position. *Id.* at 2:17–21. Cage body 1010 is generally rectangular in cross-section and includes upper portion 1012 and lower portion 1018 (see Fig. 2B), the outer

surfaces of which are joined together by hinge 1070. *Id.* at 4:40–45. As seen from a top view, cage body 1010 also includes an opening or window, as depicted in Figures 5A and 5B, reproduced below.

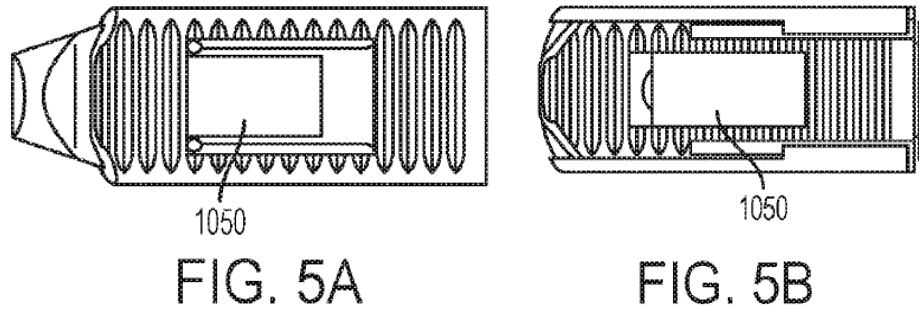


Figure 5A is a top plan view of the expandable cage of Figure 1A in the unexpanded position, and Figure 5B is a top plan view of the expandable cage of Figure 1A in the expanded position. *Id.* at 2:37–40.

The '575 patent explains that window 1050 depicted in Figures 5A and 5B is for receiving bone fusion material. *Id.* at 4:50.

Cage assembly 1000 also includes elongate expander 1032 that, when pulled proximally and into a cavity of cage body 1010, will cause upper and lower portions 1012, 1018 of the cage body 1010 to expand or spread open vertically relative to one another, while also allowing upper and lower portions 1012, 1018 to rotate about hinge 1070 thereby changing the angle of upper portion 1012 with respect to lower portion 1018. *Id.* at 5:23–31. An exemplary expander 1032 is depicted in Figure 7, reproduced below.

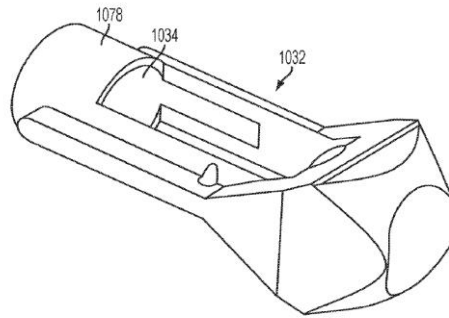


FIG. 7

Figure 7 is a perspective view of an expander for use in an expandable cage. *Id.* at 2:45–46.

Expander 1032 includes a proximal end having proximal portion 1078, which is visible through window 1050 in the unexpanded position of Figure 1A. *Id.* at 4:66–5:2. Expander 1032 also includes opening 1034. *Id.* at Fig. 7.

C. Illustrative Claim

Claims 1 and 8 are the independent claims challenged by Petitioner in this proceeding. Independent claim 1, reproduced below, is illustrative of the subject matter:

1. [a] An expandable cage for insertion into an intervertebral space, the expandable cage comprising:
 - [b] a cage having an upper portion and a lower portion, the upper portion having an upper bone contact surface and an upper portion lower surface, the lower portion having a lower bone contact surface and a lower portion upper surface,
 - [c] wherein the upper portion and the lower portion each define a window configured to permit bone growth therethrough;
 - [d] an elongate expander positioned in a cavity or an internal space therebetween the upper portion lower

surface and the lower portion upper surface, the elongate expander having a distal or leading end, a proximal or trailing end and a pair of side surfaces connecting the distal end and the proximal end having an unobstructed internal space or opening therebetween defining a window therethrough,

[e] wherein longitudinal translation of the elongate expander causes the expander to act upon portions of the upper portion and the lower portion to expand the cage body by separating at least a portion of the upper portion from at least a portion of the lower portion,

[f] wherein, in an expanded position, the windows in each of the upper portion, lower portion, and elongate expander are open and unobstructed with respect to one another when viewed from a top view.

Ex. 1001, 8:10–34 (formatting, bracketing, and lettering added for reference convenience). Claim elements 1[c], 1[d], and 1[f] identify four windows. Element 1[c] refers to an upper portion and a lower portion with each having a window. For ease of reference, we refer to the window that is part of the upper portion as the upper window and the window that is part of the lower portion as the lower window. Element 1[d] refers to the window of the elongate expander, which we refer to as the elongate expander window. Element 1[f] refers to a fourth window corresponding to an alignment between the lower window, the expander window, and the upper window, which we refer to as the aligned window.

Claim 8, the only other independent claim, also is directed to an expandable cage, and includes similar limitations to those of claim 1 and additionally includes an aperture in the elongate expander to permit introduction of bone growth material into the expandable cage, and a cap or

set screw inserted into the aperture to contain the bone growth material. *Id.* at 8:57–9:27.

D. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–9 of the '575 patent are unpatentable based on the following eight grounds. Pet. 16–17.

Ground	Claim(s) Challenged	35 U.S.C. § ¹	References/Basis
1	1–7	102(a)	Greenhalgh ²
2	8, 9	103	Greenhalgh
3	8, 9	103	Greenhalgh, Lynn ³
4	8, 9	103	Greenhalgh, Weiman ⁴
5	1–9	102(a)	Weiman
6	1–9	103	Weiman
7	1, 4–6, 8, 9	102(a)	Glerum ⁵
8	8, 9	103	Glerum

Petitioner also relies upon the declaration of Brad Culbert (Ex. 1003) to support its contentions.

¹ In the Institution Decision we determined that the '575 patent is not entitled to the benefit of the filing date of the '729 provisional application (August 8, 2012). *See* Dec. 13; *see also* PO Sur-reply 1; Tr. 12:6–22. Therefore, we apply the AIA versions of 35 U.S.C. §§ 102 and 103.

² US 8,382,842 B2 issued February 26, 2013. Ex. 1004.

³ US 8,343,224 B2 issued January 1, 2013. Ex. 1007.

⁴ US 8,852,279 B2 issued October 7, 2014. Ex. 1005.

⁵ US 8,062,375 B2 issued November 22, 2011. Ex. 1006.

Patent Owner relies on the Declarations of Hassan A. Serhan, Ph.D. to support their contentions. Patent Owner relies on the First Declaration⁶ of Dr. Serhan (Ex. 2001); the Third Declaration of Dr. Serhan (Ex. 2039), and the Fourth Declaration of Dr. Serhan in support of the Motion to Amend Reply (Ex. 2043). Patent Owner also relies on the Declaration of Dr. James C. Robinson, M.D. (Ex. 2026).

II. ANALYSIS

A. Post Grant Review Eligibility

In the Institution Decision, we determined that “that the ’575 patent is not entitled to the benefit of the filing date of the ’729 provisional application (August 8, 2012), and, thus, the ’575 patent is eligible for post-grant review.” Dec. 13.

In the Sur-reply, Patent Owner “withdraws its assertion that Petitioner failed to establish that any claim in the ’575 Patent or its parents has or had priority under AIA § 3(n)(1) and that the Board thus lacked authority to issue the Institution Decision (D.I.).” PO Sur-reply 1; see Tr. 12:6–22.

Accordingly, there is no dispute that the ’575 patent is eligible for post-grant review.

B. Level of Ordinary Skill in the Art

The parties generally agree that a person of ordinary skill in the art would have been a mechanical or biomedical engineer with several years of

⁶ We note that a Second Dr. Serhan Declaration is referenced in one of Patent Owner’s exhibit lists, but this document was never filed in this proceeding. See Tr. 33:15–25.

experience or an orthopedic surgeon or neurosurgeon with experience designing or developing medical devices. Pet. 18–19; PO Resp. 31. On this record, we adopt the parties’ definition of the level of skill in the art. We further note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

C. Claim Construction

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.200(b) (2019). This standard requires that we construe claims “in accordance with the ordinary and customary meaning of such claim[s] as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an AIA trial proceeding).

Petitioner proposes construction for several claim terms: “proximal,” “distal,” “open and unobstructed,” “keyed distal end,” and “configured to permit.” Pet. 19–30. Patent Owner agrees with Petitioner’s proposed

constructions except for “keyed distal end,” but agrees with the construction of “keyed distal end” as set out in the Institution Decision. PO Resp. 32; see Dec. 19–20; Tr. 34:5–8. Patent Owner provides further briefing for the terms “expander expands the cage” and “unobstructed.” *Id.* Below we repeat the construction for “keyed distal end” and address the terms “expander expands the cage” and “unobstructed.” We find no other term requires an express construction.

1. *“keyed distal end”*

For purposes of the Institution Decision we determined “keyed distal end” to mean that “the distal end is sized and shaped to fit at least partially within a distal cavity and is sized and shaped to engage corresponding surfaces on the upper and lower portions.” See Dec. 19–20. The parties did not dispute this construction after institution and we adopt it for this Decision. See Tr. 7:14–20, 34:5–8; PO Resp. 32.

2. *“longitudinal translation of the elongate expander causes the expander to act upon portions of the upper portion and the lower portion to expand the cage body by separating at least a portion of the upper portion from at least a portion of the lower portion”*

Independent claims 1 and 8 recite that “longitudinal translation of the elongate expander causes the expander to act upon portions of the upper portion and the lower portion to expand the cage body by separating at least a portion of the upper portion from at least a portion of the lower portion.” We refer to this limitation using the shorthand “expander expands the cage.”

Patent Owner argues that as the elongate expander is moved horizontally between the upper portion and lower portion of the cage, “[s]eparation of the upper portion and the lower portion is the result of the expander acting upon the upper and lower portions such that they both

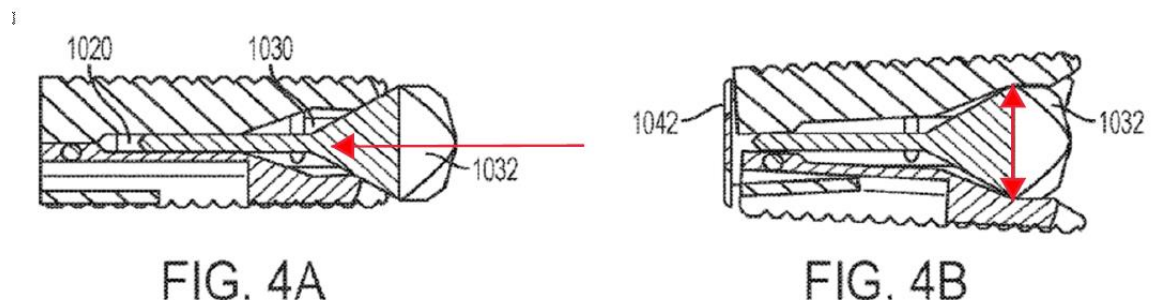
move, referred to herein as ‘bidirectional cage expansion.’” PO Resp. 33–34. Therefore, Patent Owner urges that “expander expands the cage” should be construed to “require both portions to **move** so that they are expanded or spread open, separated, and are driven apart.” *Id.* at 34. Patent Owner argues that

A construction of the limitation covering movement of just an upper portion or just lower portion would require ignoring the fact that every embodiment enables the cage body to expand only by moving the upper and the lower portions. Such unidirectional cage expansion is **physically impossible** for the embodiments disclosed in the ’575 Patent because longitudinal translation of the elongate expander always causes the two portions, which are hinged at the same axis, to pivot at that axis such that movement of both portions is **always** the result.

PO Resp. 35 (citing Ex. 2043 ¶ 38 (Serhan 3rd Decl.)).

Petitioner disagrees that “act upon” in reference to “expander expands the cage” requires that both upper and lower portion of the cage body need to move. Reply 2.

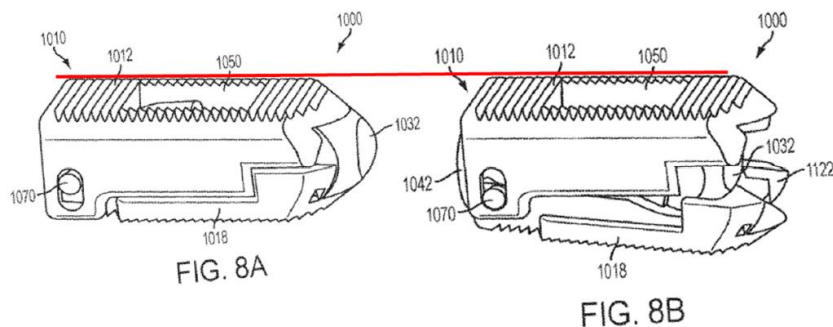
Specifically, Petitioner asserts that the Specification illustrates that the expander “acts upon” the upper and lower portions by making contact with the portions and causes the portions to separate (i.e., move further apart):



Reply 2 (citing Ex. 1001, Figs. 4A-4B). Petitioner contends that Patent Owner’s citations to the Specification “do not state, let alone require, that

the expander moves both portions. Rather, the citations merely reflect relative movement between the upper and lower portions.” Reply 2–3. Specifically, Petitioner explains that unidirectional movement of a hinged object is possible depending on the environment the object is surrounded by. Petitioner explains as follows:

[i]f the implant’s upper surface abuts a truly static intervertebral body (see red line below), then only the lower surface can move[.]. (See e.g., Ex. 2042, 122:8-15 (a surface abutting intervertebral body cannot move).)



Reply 4.

We note that “act upon” is not defined in the Specification of the ’575 patent. “Act upon” appears for the first time in claim 1 of the ’575 patent. The Specification describes that “the cage assembly may comprise an expander such as an expansion screw or a shim which, when inserted, selectively expands the body of the cage assembly to a desired size.” Ex. 1001, 4:26–29. The Specification further describes that “translation of the elongate expander proximally toward the trailing end expands the cage body by separating the *at least a portion of the upper portion from at least a portion of the lower portion.*” *Id.* at 6:56–59. (emphasis added).

We determine that “expander expands the cage” is construed in light of the Specification to mean that the expander acts upon both the upper and

lower portion of the cage to move the upper and lower portions further apart. We note, however, there is no requirement that each portion is moved away from the longitudinal expander by the same amount.

3. “*unobstructed*”

The independent claims each recite that “in an expanded position, the windows in each of the upper portion, lower portion, and elongate expander are open and **unobstructed** with respect to one another when viewed from a top view.” PO Resp. 37. According to Patent Owner, “unobstructed means ‘there are no features lying in the path and blocking the windows.’” *Id.* (citing Ex. 1002 at 29) (emphasis removed); Ex. 1021, 88:5–89:2; Ex. 2001 ¶¶ 99–100, 104; *see* Tr. 40:19–41:11.

An annotated view of Figure 5A and 5B of the ’575 patent is reproduced below:

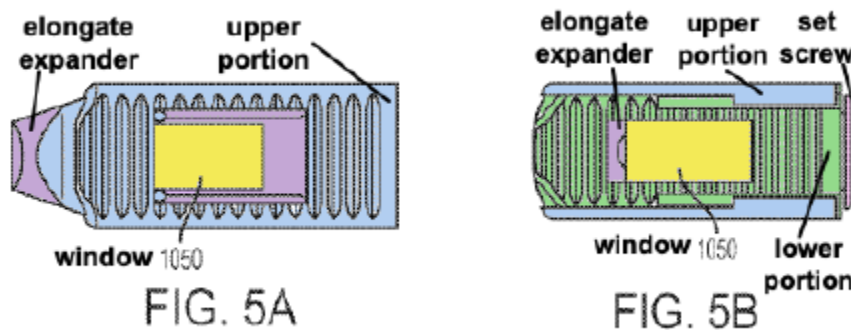


Figure 5A shows a cage in the unexpanded position from the top view and Figure 5B shows a cage in the expanded position from the bottom view. PO Reply 9; Ex. 1001, 2:37–40, Figures 5A and 5B; Tr. 36:17–25; *see also* Pet. 24–25; Ex. 1003 ¶¶ 68–71, ¶ 69 (“Despite the intrusion by the elongate expander, the three aligned windows [yellow] are open and unobstructed because there are no features lying in the path and blocking the windows.”).

Petitioner agrees that “unobstructed” means “there are no features lying in the path and blocking the windows.” Reply 4 (citing PO Reply 38; Ex. 2043 ¶ 6); Pet. 20 (“The Board should construe ‘unobstructed’ to mean ‘there are no features lying in the path and blocking the windows.’” (citing Ex. 1003 ¶ 71)).

The Specification does not define “unobstructed” or “obstructed.” Based on the disclosure in the Specification, the prosecution history,⁷ and the annotated Figure 5A and 5B above, the term “unobstructed” is understood to mean that there are no obstacles or structures lying in the path of the window created by the upper portion, lower portion, and elongate expander that would impede the view through the window. Figure 5B does not show any features that impede the view through the aligned window and thereby shows an “unobstructed view.” Tr. 40:20–41:11, *see id.* 41:5–6 (“Figure 5B shows nothing extending into the window, and that’s the only

⁷ Petitioner explains that “the plain meaning of an ‘open’ window is well understood to be a state allowing passage through the window.” Pet. 21 (citing Ex. 1003 ¶ 63). According to Petitioner, Patent Owner expressly defined “unobstructed” during prosecution to “mean there are no features lying in the path and blocking the window.” *Id.* at 21–22. Patent Owner acknowledges that the term “unobstructed” was added during prosecution in order to distinguish over Baynham (US 2007/0270968 A1, published Nov. 22, 2007). PO Resp. 36–37; Ex. 1002, 29–30. The only example of an obstructing feature identified during prosecution is an axle (or jack screw) that extends down the center of the opening which acts like a bar. *Id.* at 22 (citing Ex. 1002, 29–30); *see* Tr. 41:5–8 (“Figure 5B [of the ’575 patent] shows nothing extending into the window, and that’s the only support that there is. There’s no[] qualifying language in the specification that would allow a retreat to specify a particular amount that was considered acceptable.”)

support that there is.”). Unobstructed does not refer to the entirety of each window, but rather where they overlap relative to one another.

We determine that “unobstructed” means “there are no features lying in the path and blocking the window.”

D. Alleged Anticipation of Claims 1–7 based on Greenhalgh (Ex. 1004)

Petitioner contends that claims 1–7 are unpatentable as anticipated by Greenhalgh. Pet. 30–56. Patent Owner opposes. PO Resp. 40–48.

1. Overview of Greenhalgh

Greenhalgh is titled “Expandable Support Device and Method of Use” and relates to “devices for providing support for biological tissue, for example to fuse vertebral bodies, repair herniated discs, and/or repair spinal compression fractures, and methods of using the same.” Ex. 1004, code (54); 1:14–17. In particular, the expandable device can be filled with a biocompatible material such as bone growth factors, to provide support, fixation and improved bone structure. *Id.* at 3:18–26. An exemplary expandable device is depicted in Figure 1a of Greenhalgh, reproduced below.

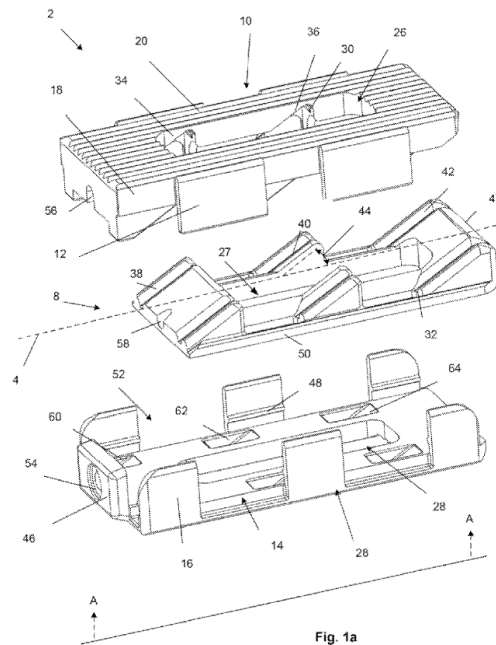


Figure 1a is an exploded view of an expandable device. Ex. 1004, 3:52–53. Expandable device 2 includes base or bottom 6, middle 8, and top 10. *Id.* at 4:56–58. Greenhalgh explains that height expansion that moves top 10 away from base 6 occurs when middle 8 is slid with respect to base 6 toward the first side. *Id.* at 7:17–21; Figs. 5a–5c. Top 10 includes port 26, middle 8 includes port 27 and base 6 includes port 28. *Id.* at 5:39–41. Top port 26, middle port 27 and base port 28 substantially align transverse with longitudinal axis 4, as seen in Figures 4a and 4b, reproduced below.

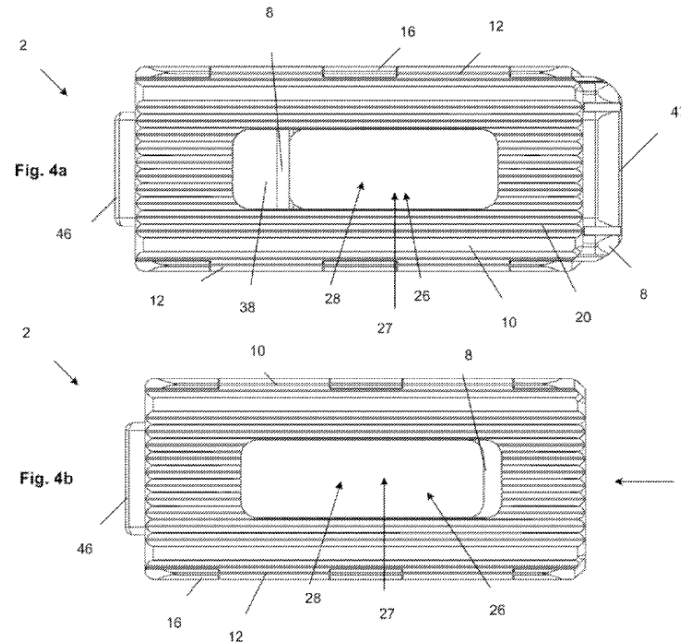
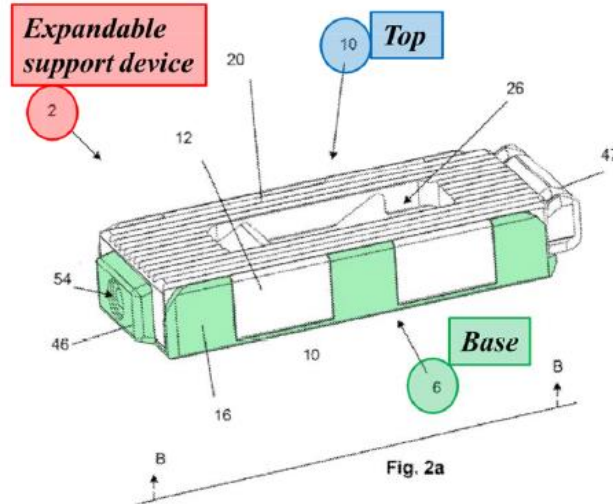


Figure 4a is a top view of a device in a height-contracted configuration, and Figure 4b is a top view of the device in a height-expanded configuration. *Id.* at 3:61–64. “The top/middle/base ports form a concurrent vertical port through the device 2.” *Id.* at 7:1–2. This concurrent vertical port can be filled with a bone growth material. *Id.* at 7:2–4. Figure 4a depicts the concurrent vertical port partially obstructed by middle 8, including middle first ramp 38, when device 2 is in a height-contracted configuration, and Figure 4b depicts the concurrent vertical port less obstructed, or substantially unobstructed when device 2 is in a height-expanded configuration. *Id.* at 7:4–9.

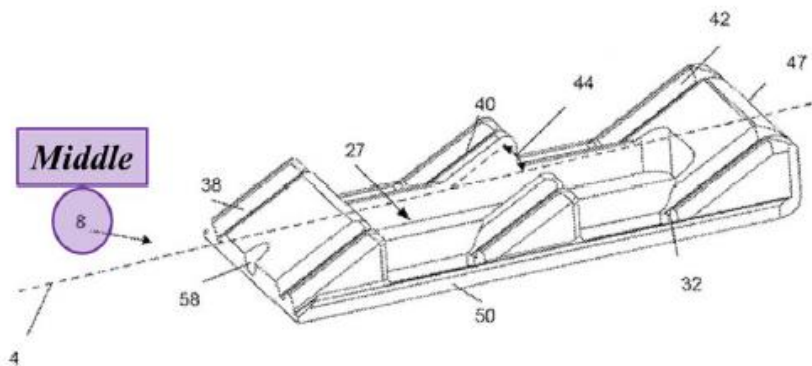
2. Analysis of Independent Claim 1

Greenhalgh meets elements 1a–1d, and 1f of claim 1. *See* Pet. 31–39, 42–45; Dec. 24–36. Briefly, Greenhalgh’s expandable support device has a base and a top. Figure 2a of Greenhalgh as annotated by Petitioner reproduced below:



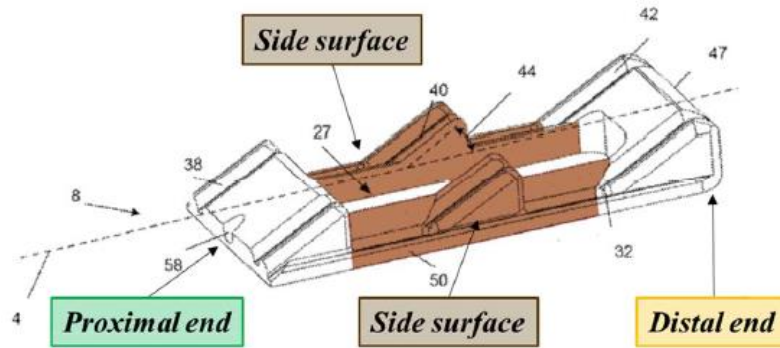
“Greenhalgh’s expandable support device 2 [red] has a base 6 [green] and a top 10 [blue].” Pet. 32 (citing Ex. 1004, 4:56–58 (“The expandable support device 2 can have a base or bottom 6 (base and bottom are used interchangeably), a middle 8, and a top 10.”))

Greenhalgh’s expandable support device has a middle part that is inserted into the expanding device between the base and the top. An excerpt of Figure 1a of Greenhalgh as annotated by Petitioner is reproduced below:



The expandable support device includes middle 8 part, shown as purple above, and is elongate because it is longer than it is wide and acts upon the top and bottom to expand the support device. Pet. 36 (citing Ex. 1004, 4:56–67; Ex. 1003 ¶ 89).

The same excerpt of Figure 1a of Greenhalgh as further annotated by Petitioner showing additional details is reproduced below:



Pet. 37 (citing 1004, 6:66–7:9; Ex. 1003 ¶ 89). The middle 8 part of the expandable support device as shown has “a distal or leading end [orange], a proximal or trailing end [green], and a pair of side surfaces connecting the proximal and distal ends [brown].” *Id.* at 36 (citing Ex. 1004, 4:56–67) (alteration in original).

Petitioner’s annotated Figures 4A and 4B of Greenhalgh are reproduced below and show an unobstructed window:

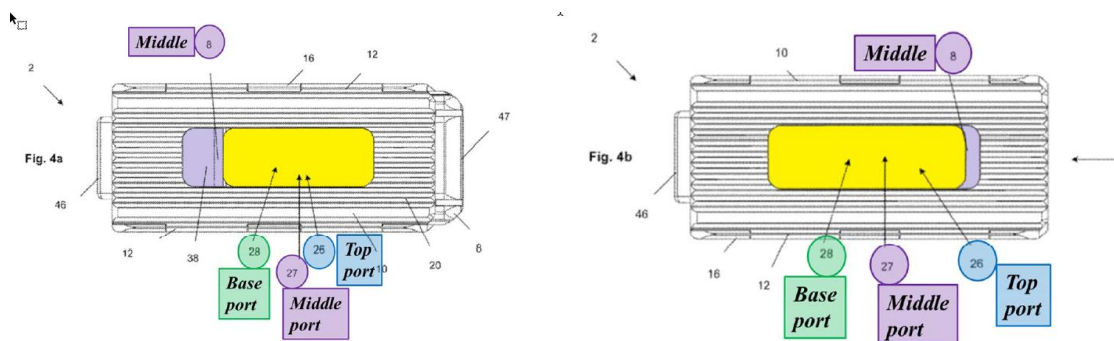


Figure 4A (shown on left) and Figure 4B (shown on right) shows the top port [blue], middle port [purple], and base port [green] of Greenhalgh’s expandable support device. Pet. 46–47. The combinations of the top port, middle port, and bottom port “form a concurrent vertical port [yellow] through device 2,” were Figure 4A is in the height-contracted configuration

and Figure 4B is in the height -expanded configuration. Pet. 45–45 (citing Ex. 1004, 7:1–9). Patent Owner does not dispute that the concurrent vertical port of Greenhalgh meets the unobstructed aligned widow limitation of claim element 1[f]. Tr. 44:24–45:5, *see id.* at 45:11–12 (“We agree that Greenhalgh shows an open and unobstructed window.”).

The parties do not dispute that Greenhalgh discloses a cage device for insertion into intervertebral space that contains an aligned window that is open and unobstructed. *See* Pet. 30–56; PO Resp. 40–43; Tr. 26:7–9 (“there’s only one dispute, and that’s whether the longitudinal translation of the elongate expander causes the expander to act upon the portions of the upper and lower portions of the cage.”), *see id.* at 44:24–45:5. Thus, the only dispute is whether Greenhalgh’s elongate expander “acts upon” the upper portion and lower portion of the cage body as recited in claim element 1e.

We address how Greenhalgh meets the limitation requiring that the elongate expanders acts upon both the top and bottom portion of the cage as recited in claim element 1e below.

a) Expander Expands the Cage (Element 1e)

Petitioner contends that Greenhalgh discloses an elongate element that acts upon both top and base. Pet. 39–42; *see* Reply 1–4.

Patent Owner argues that Greenhalgh does not disclose moving the base and top apart in a bidirectional fashion. PO Resp. 41–48. Specifically, Patent Owner argues that “every embodiment depicted in Greenhalgh longitudinally translates the middle 8 to move only the top 10 and not the base 6 for unidirectional cage expansion only.” *Id.* at 41. According to Patent Owner, “Greenhalgh does not disclose cage expansion by moving the

top and the bottom of the cage body (referred to herein as ‘bidirectional cage expansion’).” *Id.* at 42.

[Patent Owner] disagrees with Petitioner’s assertion that ‘the middle rail 50 acts upon the base (i.e., holds the base) to prevent the base 6 from separating from the middle 8.’ Pet. at 42. Base rail 46 holds the middle rail not the other way around and merely holding something does not equate to ‘act upon’ within the scope of the ‘Expander Expands the Cage’ limitation.

PO Resp. 42–43. Patent Owner argues that “the claim language says, ‘act upon.’ That requires action. And the action is not in the Newtonian physics sense of the Third Law.”⁸ Tr. 46:25–47:1.

Greenhalgh discloses that the support device is expanded by translating the middle component in the longitudinal direction. Ex. 1004, 2:55–59 (“The top and/or middle and/or bottom components can have ramps or wedges that produce an opposing force to expand the device when the top and/or middle and/or bottom components are translated relative to each other in the longitudinal direction.”), *id.* at 6:44–46 (“the device can have a height adjusted configuration. The middle 8 can be slidably translated toward the first end.”), *id.* at 7:17–23 (“the height expansion, as shown by arrow, of the top 10 away from the base 6. The height expansion can occur when the device 2 is longitudinally compressed, and/or when the middle 8 is slid with respect to the base 6 toward the first side.”); *see id.* Figs. 5A–5C, 17, 26.

We first address Patent Owner’s argument that Greenhalgh does not disclose bidirectional cage expansion. We note that “bidirectional” does not

⁸ Newton’s third law states that for every action (force) in nature there is an equal and opposite reaction.

appear in the language of claim 1 of the '575 patent nor does it appear anywhere in the Specification of the '575 patent. All that is required by claim 1 is for the cage body to expand, which requires “the expander to act upon portions of the upper portion and the lower portion to expand the cage body by separating at least a portion of the upper portion from at least a portion of the lower portion.” Ex. 1001, 8:27–31. Thus, separation of the upper portion and lower portion upon the longitudinal translation of the elongate expander is all that is required to meet the claim element.

Greenhalgh discloses separation of the upper and lower portion of the cage, explaining that “[t]he height expansion can occur when the device 2 is longitudinally compressed, and/or when the middle 8 is slid with respect to the base 6 toward the first side.” Ex. 1004, 7:17–21. Greenhalgh’s Figure 26 is reproduced below:

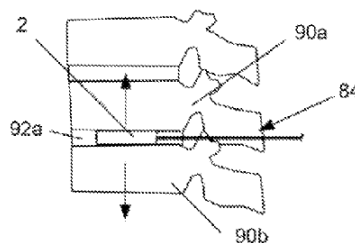


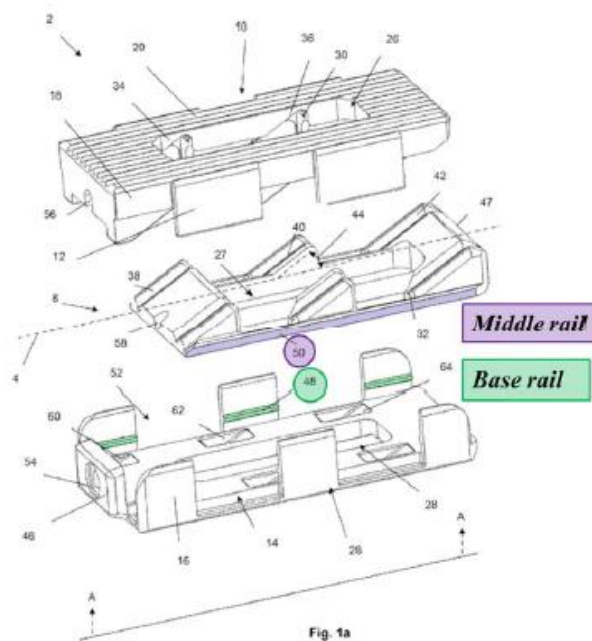
Fig. 26

“Fig. 26 illustrates that the expandable support device 2 can be rapidly expanded, as shown by arrows, in the space of disc 92a.” Ex. 1004, 13:34–36; Ex. 1003 ¶ 119; Pet. 60.

Next, we address Patent Owner’s argument that Greenhalgh does not disclose that the middle rail acts upon both the top and bottom. Specifically, Patent Owner argues that “Greenhalgh does not disclose cage expansion by moving the top and the bottom of the cage body.” PO Resp. 42. Patent Owner argues that “[t]his rail configuration prevents base 6 and middle 8

from moving upward or downward relative to each other as admitted by Mr. Culbert.” PO Resp. 42 (citing Ex. 2042, 122:16–18). Patent Owner argues that “[b]ase rail 46 holds the middle rail not the other way around and merely holding something does not equate to ‘act upon’ within the scope of the ‘Expander Expands the Cage’ limitation.” PO Resp. 42–43.

Greenhalgh’s cage body expands by separating the top from the base. Greenhalgh teaches that the insertion of element 8 between elements top 10 and base 6 expands the cage. See Ex. 1004, Fig. 1a, *see also id.* Fig. 2, 3, 5. Petitioner’s annotated figure 1a of Greenhalgh is reproduced below:



Greenhalgh annotated Figure 1a is reproduced above and shows a middle rail in purple and the base rail in green. See Pet. 42. With reference to annotated Figure 1a of Greenhalgh, Petitioner explains:

Even in embodiments where the base 6 does not have ramps, the middle 8 still will “act upon” the base to expand the cage body, as claimed. ([Ex. 1003] ¶ 96.) Greenhalgh discloses that the base has a base rail 48 [green]. (Ex. 1004, 6:14.) The

middle has a corresponding middle rail 50 [purple] that “can be slidably fed onto or under the base rail 48.” (*Id.*, 6:14-16.) The base rail 48 and middle rail 50 thereby “constrain relative motion between the middle 8 and the base 6 to the dimension of the longitudinal axis 4.” (*Id.*, 6:16-18.)

Thus, the middle rail 50 acts upon the base (i.e., holds the base) to prevent the base 6 from separating from the middle 8, while still permitting the base to translate longitudinally. (*Id.*, 6:16-18.) This sliding engagement allows the cage body to expand by separating the top from the base. (Ex. 1003, ¶ 96.)

Pet. 41–42.

We agree with Petitioner that even if base 6 is held in close proximity to middle rail element 8 by the base rail 46, the middle rail still acts upon both the base and top to expand the cage. Pet. 40–41 (citing Ex. 1003 ¶ 96 (“Even in embodiments where the base 6 does not have ramps, the middle 8 still acts upon the base to expand the cage body. . . . *This sliding engagement allows the cage body to expand by separating the top from the base.*” (emphasis added))). Petitioner’s expert, Mr. Culbert explains that it is the environment surrounding the device that will determine whether the device can move in both directions. See Ex. 2042, 122:10–15 (“It’s a relative thing. We have -- base 6 is resting on the bottom of the intervertebral body. Then it’s not going to move down. But if it’s sitting in the middle of the disc space, they’re going to move towards each vertebral body relative to each other.”); see Ex. 1004, 12:30–35, Fig. 17. In other words, if you force a wedge between two objects to pry the objects apart the force is applied in both directions, unless of course as Petitioner’s expert, Mr. Culbert, explains one object is resting on an immovable surface. *Id.* The elongate expander of

Greenhalgh, just like a wedge, applies force, i.e. acts upon, both the top and bottom in order to move the top and bottom apart.

For the foregoing reasons, we determine that Petitioner has shown that Greenhalgh anticipates claim element 1e.

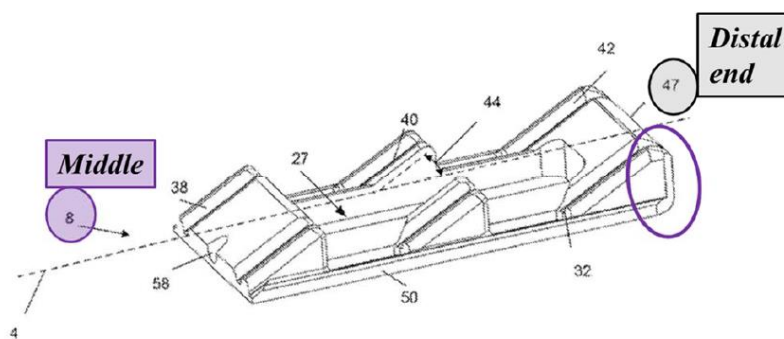
b) Summary of Claim 1

Petitioner has demonstrated that claim 1 of the '575 patent is anticipated by Greenhalgh.

3. Analysis of Dependent Claim 5

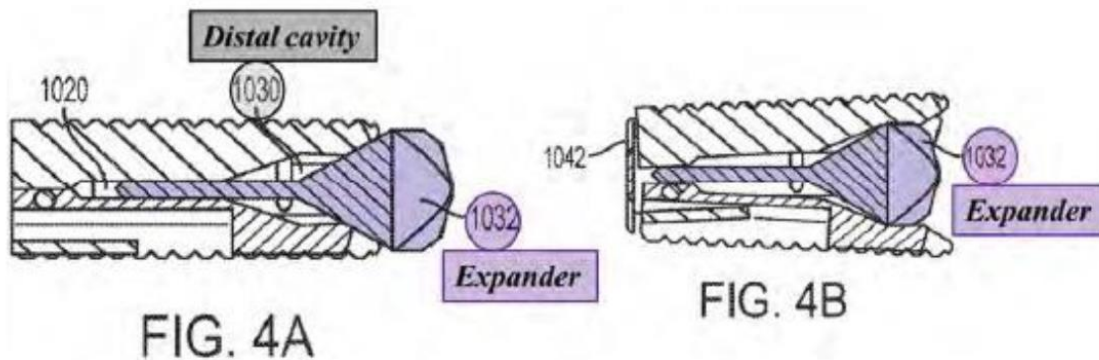
Petitioner contends claim 5 is anticipated by Greenhalgh. Pet. 52–53.

Claim 5 recites “wherein the keyed distal end has tapered sides.” Ex. 1001, 8:49–50. As discussed above (see Section II.C.1), we determine that “keyed distal end” is construed in light of the Specification to mean that “the distal end is sized and shaped to fit at least partially within a distal cavity and is sized and shaped to engage corresponding surfaces on the upper and lower portions.” Petitioner identifies a tapered surface on a keyed distal end, as shown in annotated Figure 1a below:



Annotated Figure 1a of Greenhalgh shows the elongated expander with a keyed distal end. Pet. 53 (citing Ex. 1003 ¶¶ 107–108). The highlighted distal end shows tapers on the front and back of Greenhalgh’s elongate expander.

Patent Owner argues that Petitioner’s interpretation of tapered sides does not comport with the ’575 patent description of the invention. See PO Resp. 46–48. Patent Owner provides annotated Figures 4A and 4B, reproduced below, of the ’575 patent to “emphasize the function of the tapered sides, engaging corresponding surfaces on the upper and lower portions to drive them apart.” PO Resp. 47.



The annotated Figure 4a and 4b. PO Resp. 48. The figure shows the expander before and after insertion into the cage body.

The ’575 patent describes that the expander 1032 may be a keyed shim. “[T]he key is generally conical in cross- section with a rectangular or square end, like the head of a bolt, and *tapered on both sides*. The key shape on the distal portion may be sized and shaped to fit within a distal cavity.” Ex. 1001, 4:54–57 (emphasis added). Here, the recitation “wherein the keyed distal end has tapered sides” does not provide guidance on which surface of the keyed distal end the taper needs to be located on and the ’575 patent further suggests that the taper can be on both sides. It is not proper to import limitations from the Specification into the claims. *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007); see also Reply 12 (arguing that the claims do not require that the tapered sides engage corresponding surfaces, and “[t]herefore, the Board should reject PO’s

improper attempt to read limitations from the specification into the claims.”).

Based on the record, we find that Petitioner has demonstrated that claim 5 of the ’575 patent is anticipated by Greenhalgh’s elongate expander.

4. Analysis of Claims 2–4, 6, and 7

Petitioner sets forth argument and evidence for its assertion that claims 2–4, 6, and 7 are anticipated by Greenhalgh. Pet. 45–51, 53–56. Patent Owner does not present arguments in the Patent Owner’s Response addressing specific merits of Petitioner’s contention, separately from Patent Owner’s arguments as to claims 1 and 5. See PO Resp. 40–48.

Based on our independent review of the evidence in this record, we determine that Petitioner has demonstrated that claims 2–4, 6, and 7 are anticipated by Greenhalgh. See Pet. 45–51, 53–56.

5. Conclusion

Based on the evidence and arguments of record, Petitioner has demonstrated that claims 1–7 of the ’575 patent are anticipated by Greenhalgh.

E. Alleged Obviousness of Claims 8 and 9 over Greenhalgh

Petitioner contends that Claims 8 and 9 are unpatentable as obvious over Greenhalgh. Pet. 66–69. Patent Owner argues that Greenhalgh does not teach a cap screw or teach packing through the deployment port. PO Resp. 51–59.

1. *Claim 8*

a) Aperture In Communication With The Cavity

Petitioner acknowledges that “Greenhalgh does not expressly disclose how the surgeon fills the vertical port when the device is in the deployed configuration.” Pet. 59. According to Petitioner, a person of ordinary skill in the art “would have understood that the only way to pack the internal cavity when the device is in the deployed configuration would be through the first side outer port 54 and first side inner port 58.” *Id.* at 61 (citing Ex. 1003 ¶ 120).

Patent Owner argues “that Greenhalgh’s port is impractically small and that it would not be used to deliver BG [bone growth] material into the interior of the device.” PO Resp. 56 (citing Ex. 2001 ¶¶ 157, 162–171). Patent Owner’s expert, Dr. Serhan, relies on Greenhalgh’s unexpanded device height of 4 mm for concluding that the port could be no more than 1.0 mm and thereby at most fit a “20 gauge needle (having a nominal O.D. of 0.91 mm).” Ex. 2001 ¶ 167, *see also id.* ¶ 166. Patent Owner argues that the smallest sized needle “a surgeon would use is a 16 gauge (1.65 mm diameter) and more like a 14 gauge needle,” and this sized needle would not fit the Greenhalgh port. PO Resp. 57 (citing Ex. 2001 ¶ 167). According to Patent Owner, Mr. Culbert, Petitioner’s expert, agrees that “that a typical syringe used for delivering bone growth material, such as a 5-ml or a 10-ml syringe, has an inner diameter of about 2 millimeters.” PO Resp. 57 (citing Ex. 2042, 53:11–21). Patent Owner argues that “[b]ecause Greenhalgh’s port 54 is designed for accepting a deployment tool/locking rod—not for packing bone growth material, the port is narrow and long, thus essentially eliminating concerns about flow of BG material via port 54.” PO Resp. 58.

Petitioner counters that Patent Owner's argument "is inconsistent with Greenhalgh's express teaching that the expandable support device can be filled with bone growth material" when "in a deployed configuration in vivo." Reply 13 (citing Ex. 1004, 9:30–35).

We agree with Petitioner that Greenhalgh teaches that port 58 is in communication with port 27 that forms part of the cavity. Pet. 57–58 (citing Ex. 1004, Fig. 1a, 1b, 2b, 3b; Ex. 1003 ¶ 117). Greenhalgh also teaches adding filler material into the cavity of the expanded device.

When the expandable support device 2 is in a deployed configuration in vivo, the expandable support device 2 can be partially or substantially filled with a liquid, gel, or solid (e.g., in small parts or granules) filler material, or combinations thereof, such as bone morphogenic powder or any other material disclosed herein or combinations thereof. The filler material can contact or be in near contact with the surrounding tissue near the edge of the ports.

Ex. 1004, 9:30–37. Petitioner's expert, Mr. Culbert, explains that Greenhalgh's "deployed configuration" is the expanded configuration. Ex. 1003 ¶ 118. Because the surgeon would have limited access to the cavity once the device is in the deployed position, adding the bone growth material through any accessible ports, including port 58, is obvious. See Ex. 1003 ¶¶ 119–120, 122.

Greenhalgh's unexpanded device has a height of 4–8 mm. Reply 13–14; PO Resp. 56; Ex. 1004, 3:44–48 ("For vertebroplasty or interbody applications, the device can have an initial height or diameter from about 4 mm (0.16 in.) to about 8 mm (0.31 in.) and an expanded height or diameter from about 7 mm (0.28 in.) to about 18 mm (0.71 in.)."). Petitioner contends that contemporaneously available interbody fusion devices in the art had an

unexpanded height of 8 mm. Reply 14 (citing Ex. 2042, 23:12–22, 99:19–101:2).

We agree with Petitioner that Patent Owner’s reliance on the smallest unexpanded device of 4 mm taught by Greenhalgh, when the reference provides a range in size of 4–8 mm in the unexpanded state, does not address the full scope of the teachings disclosed in Greenhalgh. *See* Reply 15.

[A]pplying the $\frac{1}{4}$ ratio used by PO to the unexpanded height of 8 mm yields a port of 2 mm in diameter. (*See also* Ex. 2042, 101:3-16 (estimating port diameter of 3 mm).) PO’s expert testified that that [a person of ordinary skill in the art] used needles having an outer diameter of 1.65 mm to deliver “BG material.” (Ex. 2001, ¶ 167.) This testimony is consistent with Mr. Culbert’s testimony that [a person of ordinary skill in the art] could easily insert bone growth material through a 2 mm port in 2012. (Ex. 2042, 51:19–56:8, 102:1–15.) Thus, the undisputed evidence demonstrates that Greenhalgh discloses an aperture that is configured to permit packing of bone growth material.

Reply 15.

Based on the evidence and arguments of record, we find that Petitioner demonstrates by a preponderance of the evidence that Greenhalgh renders an aperture in communication with the cavity for the introduction of bone growth material as recited in claim 8 of the ’575 patent obvious.

b) Cap or Set Screw

Petitioner acknowledges that “Greenhalgh does not expressly disclose how the surgeon fills the vertical port when the device is in the deployed configuration.” Pet. 59. The deployed configuration is the expanded configuration in Greenhalgh. *Id.* (citing Ex. 1004, 3:1–7). And Greenhalgh expressly states that “[w]hen the expandable support device 2 is in a

deployed configuration in vivo, the expandable support device 2 can be partially or substantially filled with a liquid, gel, or solid (e.g., in small parts or granules) filler material, or combinations thereof, such as bone morphogenic powder or any other material disclosed herein or combinations thereof.” *Id.* (citing Ex. 1004, 9:30–35.)

Greenhalgh’s Figure 26 is reproduced below:

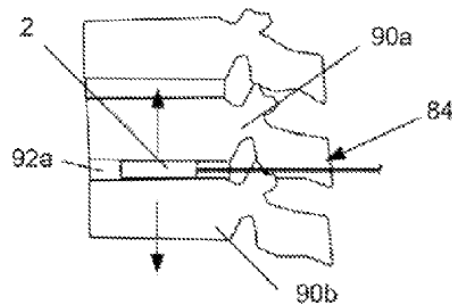
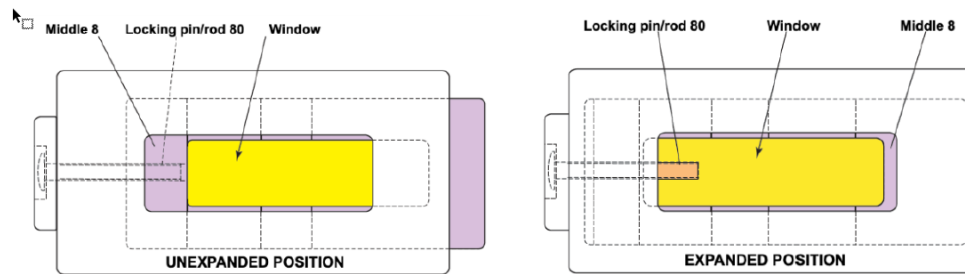


Fig. 26

“Fig. 26 illustrates that the expandable support device 2 can be rapidly expanded, as shown by arrows, in the space of disc 92a.” Ex. 1004, 13:34–36; Ex. 1003 ¶ 119; Pet. 60. Petitioner’s expert, Mr. Culbert explains that in the deployed position there is no access to the top and bottom ports to insert material, and there is limited access to the internal cavity of the device. Pet. 60 (citing Ex. 1003 ¶ 120). “[A] person of ordinary skill in the art would have understood that the only way to pack the internal cavity when the device is in the deployed configuration would be through the first side outer port 54 and first side inner port 58.” Ex. 1003 ¶ 120.

Patent Owner argues that “any use of a rod as taught by Greenhalgh as a cap or set screw would obstruct the windows.” PO Resp. 51. “As provided below, if a locking pin 80 is positioned in inner port 58 to prevent cage collapse then the locking pin 80 will obstruct the windows.” *Id.* at 52 (citing Ex. 2001 ¶¶ 139–144; Ex. 2043 ¶¶ 10–29). Patent Owner argues that “in the

expanded position, the locking pin/rod of the hypothetical version of Embodiment #1 obstructs the windows unlike the configuration in Figure 4b[of the '575 patent].” *Id.* at 53. Patent Owner’s annotated Figure 2b of Greenhalgh is reproduced below:



Greenhalgh’s annotated Figure 2B shows that in the expanded position the locking pin rod 80 engages the middle portion and obstructs the window unlike the configuration in Figure 4B of the '575 patent. *Id.* at 53–54 (citing Ex. 2001 ¶¶ 141–143; Ex. 2043 ¶¶ 23–26). Patent Owner argues that Petitioner is relying on improper hindsight and asserting that cap 72 could somehow be separate from the deployment rod. *Id.* at 54. Patent Owner further argues that the side inner port 58 has such a small diameter and a long length that a person of ordinary skill would not be worried about the flow of bone growth material out from the inner cavity via the inner port 58 and therefore there would be no motivation to make any changes. *Id.* at 55.

Petitioner counters that Greenhalgh teaches that the deployment rod can have an attached or integral cap, and if the cap can be attached then it can also be detached. Reply 16 (citing Ex. 1003 ¶ 129). Furthermore, Petitioner contends that Mr. Culbet’s testimony with respect to aligning the ports as a reason for making the modification is un rebutted. *Id.* at 17 (citing Ex. 1003 ¶ 130). Petitioner’s expert, Mr. Culbert explains that one of ordinary skill in the art would have been motivated to use a cap that extends

into the first side inner port 58 because: “First, if the cap spanned from the first side outer port 54 to the first side inner port 58, the cap would help the base and middle aligned by preventing them from shifting vertically with respect to each other. Second, the cap would prevent bone growth material from escaping into any gap between the first side outer port and first side inner port.” Ex. 1003 ¶ 130, *see also id.* ¶ 131 (“a cap would prevent the bone growth material from escaping through the proximal openings.”); Ex. 1004, 7:25–29 (“A deployment tool and/or locking rod 70 can be inserted through the first port and the second side port 68. The deployment rod 70 can have an attached or integral deployment rod cap 72 or nut that can be outside the first port and interference fit with the wall surrounding the first port.”).

We determine that Petitioner has sufficiently established that, based on the knowledge of one of ordinary skill in the art, it would have been obvious “to insert a separate cap (i.e., not attached to the deployment rod) into the first side outer port 54” to prevent any material introduced into the cavity from leaking out. Pet. 68 (citing Ex. 1003 ¶ 129). *See In re Larson*, 340 F.2d 965, 968 (CCPA 1965) (making elements of a device integral or separable is considered an obvious design choice and does not render an invention patentable).

Based on the evidence and arguments of record, we find that Petitioner demonstrates by a preponderance of the evidence that claim 8 of the ’575 patent would have been obvious to one of ordinary skill in the art over the teachings of Greenhalgh.

2. *Claim 9*

Claim 9 recites that the expandable cage further comprises “a tool bore, coaxial with the aperture, sized and shaped to accept an expansion tool.”

Petitioner contends, and Patent Owner does not dispute, that Greenhalgh discloses a port for the insertion of an expansion tool. *See* Pet. 74–75; PO Resp. 58 (“Greenhalgh’s port 54 is designed for accepting a deployment tool/locking rod.”). The dispute is directed to the size of the port used for the insertion of bone growth material. PO Resp 58 (Greenhalgh’s port 54 is not sized “not for packing bone growth material, [a bone growth insertion] port is narrow and long, thus essentially eliminating concerns about flow of BG material via port 54.”)

For the reasons discussed above with respect to claim 8 (*see* II.E.1.a), we are not persuaded by Patent Owner’s argument that Greenhalgh’s port is not sufficiently sized for the insertion of bone growth material. Greenhalgh teaches “[a] deployment tool and/or locking rod 70 can be inserted through the first port and the second side port 68. The deployment rod 70 can have an attached or integral deployment rod cap 72 or nut that can be outside the first port and interference fit with the wall surrounding the first port.” Ex. 1004, 7:25–29. “The deployment rod is an expansion tool because the surgeon uses the rod to pull the middle proximally to expand the expandable support device 2.” Pet. 75 (citing Ex. 1004, 7:30–33; Ex. 1003 ¶ 145).

Based on the evidence and arguments of record, we find that Petitioner demonstrates by a preponderance of the evidence that claim 9 of the ’575 patent is obvious to one of ordinary skill in the art over the teachings of Greenhalgh.

F. Alleged Obviousness of Claims 8 and 9 over Greenhalgh and Lynn (Ex. 1007)

Petitioner contends that claims 8 and 9 are unpatentable as obvious over Greenhalgh and Lynn. Pet. 69–71. Patent Owner opposes. PO Resp. 59–60.

1. Overview of Lynn

Lynn is titled “Intervertebral Implants and Graft Delivery Systems and Methods” and relates to “spinal fusion, and more specifically, to spinal implants and related systems, tools and methods.” Ex. 1007, code (54), 1:15–17. Lynn discloses that implant 1100 includes port 1136 along one of the lateral side walls of implant 1100. *Id.* at 25:64–26:1. Port 1136 can be configured to receive a fill tube “for post-filling, at least partially, an interior chamber or cavity of the implant with grafting agents and/or other fill materials.” *Id.* at 26:6–8. Lynn further discloses that a cap or other sealing member 1138 can be secured to port 1136 to “help ensure that grafting and/or filler materials delivered or otherwise positioned within the interior of the implant do not escape through the port 1136.” *Id.* at 26:13–17.

2. Analysis Independent Claims 8 and 9

Petitioner contends that Lynn describes that a cannulated insertion tool assembly has the advantage of not requiring the disengagement of the insertion tool and engagement of a fill tool. Pet. 64 (citing Ex. 1007, 24:39–53; Ex. 1003 ¶ 122). Petitioner concludes that a person of ordinary skill in the art would have been “motivated to use a single tool to deliver the implant and introduce bone growth material for many reasons, including reducing trauma to the patient, shortening the overall length of the surgical

procedure, and minimizing opportunities for complications.” *Id.* at 65 (citing Ex. 1003 ¶ 124).

Patent Owner argues that because Lynn is a static device one of ordinary skill in the art would not consult Lynn to “modify Greenhalgh’s narrow and long port as used with a deployment tool/locking rod based on Lynn’s wide and short port that is ideal for easy movement of the large particles in the BG material.” PO Resp. 59. Patent Owner argues that Petitioner has not articulated how to modify Greenhalgh to have a large port in order to deliver bone graft material. *Id.* at 60 (citing Ex. 2001 ¶¶ 179–183).

We determine that Petitioner has shown that claims 8 and 9 are obvious based on the combination of Greenhalgh and Lynn. Elements in claim 8 that overlap with elements in claim 1 as they apply to Greenhalgh are addressed in our analysis above. *See above* II.D; Dec. 24–34. Lynn teaches a spinal implant having four sides and is adapted to receive at least one graft and/or fill material. Ex. 1007, Abstract. Figure 20 of Lynn, reproduced below, shows a spinal implant.

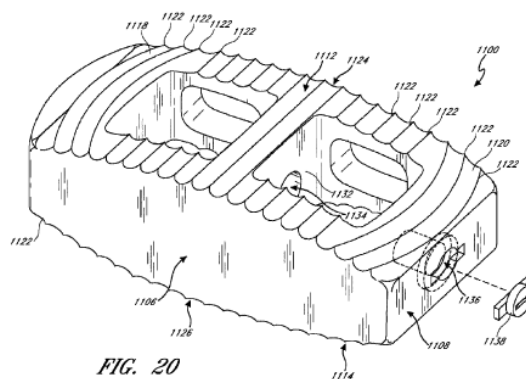


Figure 20 shows “a cap or other sealing member 1138 can be secured to the port 1136. Such a cap 1138 can help ensure that grafting and/or filler

materials delivered or otherwise positioned within the interior of the implant do not escape through the port 1136.” Ex. 1007, 26:13–17. “[P]ort 1136 can be configured to receive an implant delivery tool (e.g., to assist a surgeon in moving the implant through the patients anatomy to a target intervertebral space) [and] can serve a dual purpose related to implant positioning and graft delivery.” *Id.* at 26:3–11.

The obviousness analysis “can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Making elements of a device integral or separable is considered an obvious design choice and does not render an invention patentable. *See In re Larson*, 340 F.2d 965, 968 (CCPA 1965); *see also KSR*, 550 U.S. at 417 (“[W]hen a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.”).

Here, Petitioner’s expert Mr. Culbert explains that one of ordinary skill in the art would have been motivated to use a single tool to both deliver the implant and introduce bone growth material. Ex. 1003 ¶ 124.

Specifically, Mr. Culbert explains that “inserting a new tool into a small opening in the expandable device once the surgeon had implanted the expandable device would be very difficult and, at a minimum, very time consuming.” *Id.* Petitioner’s expert further explains that “reducing the number of tools can [save time and] also reduce trauma.” *Id.* This conclusion is supported by Lynn which suggests that the implant delivery tool can serve dual purpose of implant positioning and graft delivery. Ex. 1007, 26:3–11; Ex. 1003 ¶ 123.

Greenhalgh already teaches including bone growth material in the cage formed by the top/middle/base ports. Ex. 1004, 7:1–4. Specifically, Greenhalgh teaches that

When the expandable support device 2 is in *a deployed configuration in vivo*, the expandable support device 2 can be partially or substantially filled with a liquid, gel, or solid (e.g., in small parts or granules) filler material, or combinations thereof, such as bone morphogenic powder or any other material disclosed herein or combinations thereof. The filler material can contact or be in near contact with the surrounding tissue near the edge of the ports.

Id. at 9:30–37 (emphasis added). Although Greenhalgh does not describe how the bone growth material is inserted into the cavity once the device is positioned in the body, the reference clearly teaches that it can be filled with bone growth material after the device is deployed. *Id.* Because there are limited access points for placing material into the cavity created by the top/middle/base ports of Greenhalgh we are persuaded by Petitioner’s expert testimony that one of ordinary skill in the art would have looked to Lynn for teaching how to fill a device once deployed. Ex. 1003 ¶¶ 132–135.

We are not persuaded by Patent Owner’s argument that Petitioner has not sufficiently articulated “how Greenhalgh would be modified by Lynn to deliver BG material into the interior of the device so presumably the proposed modification is just making the ports in Greenhalgh bigger without regard to how that impacts other considerations such as the necessity of the locking rods in Greenhalgh or changes to the height due to the much bigger ports for the expandable device.” PO Resp. 60 (citing Ex. 2001 ¶¶ 179–183). Here, Petitioner’s combination is not based on bodily incorporating Lynn’s dual use tool into Greenhalgh’s device, but instead suggests that

Greenhalgh's positioning device can have dual functions like the device in Lynn. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981) ("The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art."); *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973) ("Combining the teachings of references does not involve an ability to combine their specific structures.") (emphasis omitted)).

We are also not persuaded by Patent Owner's argument that based on Lynn one of ordinary skill in the art would be discouraged from adding a larger port onto an expandable device. PO Resp. 60 (citing Ex. 1007 38–52).

By maintaining a relatively large port diameter or other dimension, a larger fill tube or conduit can be advantageously positioned through such a port. Accordingly, *the friction* associated with passing grafting and/or other fill materials through the fill tube can be *reduced*. This allows for *less strenuous delivery of grafting and/or other fill materials into the interior of an implant* (e.g., during a post-fill procedure). Accordingly, the Surgeon or other clinician performing a fill procedure can more easily deliver the necessary materials through the fill tube. Therefore, although it is somewhat counterintuitive to include a relatively large port or other openings along one or more walls of the implant (e.g., because of the likelihood of grafting and/or other filler materials leaking out of the implant). *Such an oversized port can provide one or more benefits and advantages during a fill procedure.*

Ex. 1007, 11:38–52 (emphasis added). Here, Lynn recognizes that using a large port diameter may have the disadvantage of possibly leaking implant material out from the device, but the large port comes with the advantage of decreasing the friction associated with passing grafting and/or filler

materials through the fill tube. In other words, making it less strenuous for the surgeon to add the grafting and/or filler material once the device is positioned. *See id.* Accordingly, we are not persuaded by Patent Owner's argument that Lynn discourages a person of ordinary skill in the art from making the combination with Greenhalgh.

Based on the evidence and arguments of record, we find that Petitioner demonstrates by a preponderance of the evidence that claims 8 and 9 of the '575 patent are obvious to one of ordinary skill in the art over the combined teachings of Greenhalgh and Lynn.

III. ALLEGED OTHER GROUNDS OF UNPATENTABILITY

Petitioner's other arguments include that the combination of Greenhalgh and Weiman renders claims 8 and 9 of the '575 patent obvious under 35 U.S.C. § 103(a) (Pet. 71–75); that Weiman either anticipates claims 1–9 under 35 U.S.C. § 102, or renders claims 1–9 of the '575 patent obvious under 35 U.S.C. § 103(a); and that Glerum either anticipates claims 1, 4–6, 8, and 9 under 35 U.S.C. § 102, or renders claims 8 and 9 of the '575 obvious under 35 U.S.C. § 103(a). These additional stated grounds of unpatentability challenge the same claims that we already determine are unpatentable over Greenhalgh or Greenhalgh in combination with Lynn. *See supra* Sections D, E, F (determining Petitioner has shown that claims 1–9 are unpatentable). Under the circumstances of this case, analyzing these additional grounds challenging the same claims, which we have already determined to be unpatentable, would not be an efficient use of the Board's time and resources. *See Bos. Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (non-precedential) (“We agree that the

Board need not address issues that are not necessary to the resolution of the proceeding.”).

Accordingly, we do not reach these additional anticipation or obviousness grounds.

IV. REVISED CONTINGENT MOTION TO AMEND

Patent Owner filed a Revised Contingent Motion to Amend, to cancel claims 1–9 of the ’575 patent if they are found unpatentable and proposing substitute claims 20–28. (Paper 22 (“RMTA”). For the reasons discussed above, we have determined that original claims 1–9 of the ’575 patent have been shown to be unpatentable by a preponderance of the evidence; therefore, we proceed to address Patent Owner’s Revised Contingent Motion to Amend.

As a replacement for independent claim 1, Patent Owner proposes revised contingent substitute claim 20. *See* RMTA 1–3. Revised contingent substitute claim 20 is reproduced below with annotations showing amendments to original claim 1:

20. (Contingent substitute for Claim 1) An expandable cage for insertion into an intervertebral space, the expandable cage comprising:

[20a] a cage body having an upper portion and a lower portion, the upper portion having an upper bone contact surface and an upper portion lower surface, the lower portion having a lower bone contact surface and a lower portion upper surface, wherein the upper portion and the lower portion each define a window configured to permit bone growth therethrough;

[20b] an elongate expander positioned in a cavity or an internal space therebetween the upper portion lower surface and the lower portion upper surface, the elongate expander having a distal portion with a distal or leading end of the elongate expander, a proximal portion with a proximal or trailing end of

the elongate expander, ~~and~~ a pair of side surfaces connecting the distal end and the proximal end, and having an unobstructed internal space or opening therebetween defining a window therethrough through the elongate expander such that the window of the elongate expander is framed by the distal portion, the proximal portion, and the side surfaces of the elongate expander;

[20c] wherein each of the side surfaces of the elongate expander includes a first inclined portion that interacts with the upper portion of the cage body;

[20d] wherein each of the side surfaces of the elongate expander includes a second inclined portion that interacts with the lower portion of the cage body;

[20e] wherein the elongate expander has an aperture defined in the proximal or trailing end of the elongate expander and extending through the proximal portion of the elongate expander to the window of the elongate expander, and wherein the aperture has threads; and

[20f] a screw positioned in the aperture in the proximal portion of the elongate expander, wherein the screw has threads that engage the threads of the aperture;

[20g] wherein rotation of the screw enables the threads of the screw to interact with the threads of the aperture of the elongate expander to drive longitudinal translation of the elongate expander in a first direction and causes the expander to simultaneously act upon portions of the upper portion and the lower portion to expand the cage body from an unexpanded position to an expanded position by separating at least a portion of the upper portion from at least a portion of the lower portion such that the upper portion moves upward relative to and away from the elongate expander and the lower portion moves downward relative to and away from the elongate expander, and wherein, after expansion of the cage body, the elongate expander may be longitudinally translated in a second direction, which is opposite the first direction[.];

[20h] wherein, in ~~an~~ the expanded position, the windows in each of the upper portion, lower portion, and elongate

expander are open and unobstructed with respect to one another when viewed from a top view;

[20i] wherein the screw remains in the aperture in the proximal portion of the elongate expander after longitudinal movement of the elongate expander to a final position that results in the expanded position of the cage body; and

[20j] wherein, in the expanded position and the unexpanded position, no portion of the screw extends beyond the aperture in the proximal portion of the elongate expander and into the window of the elongate expander when viewed from a top view.

RMTA, Claims App'x 1–3 (bracketing and numbering added for reference convenience).

In a post-grant review, amended claims are not added to a patent as of right, but rather must be proposed as part of a motion to amend. 35 U.S.C. § 326(d). The Board must assess the patentability of the proposed substitute claims “without placing the burden of persuasion on the patent owner.”

Aqua Prods., Inc. v. Matal, 872 F.3d 1290, 1328 (Fed. Cir. 2017) (en banc); see *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential). Patent Owner’s proposed substitute claims, however, must still meet the statutory requirements of 35 U.S.C. § 326 and the procedural requirements of 37 C.F.R. § 42.221 as a threshold matter. See USPTO’s Memorandum, Guidance On Motions to Amend in view of Aqua Products (Nov. 2017).⁹

Sufficiency of a specification’s written description is a fact question, and “the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor

⁹ https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf (last visited July 28, 2022).

had possession of the claimed subject matter as of the filing date.” *Ariad Pharm., Inc. v. Mass. Inst. of Tech.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). “And while the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement.” *Id.* at 1352 (internal citations omitted).

In the Revised Contingent Motion to Amend, Patent Owner lists citations to the ’500 application (Ex. 1002, 103–122, 142–155) as allegedly supporting each claim element of the revised proposed substitute claim 20. See RMTA 5–7. Patent Owner asserts that element 20j of the revised contingent substitute claim 20 finds support in Figures 5A–5B, 7–10 of the ’500 application. RMTA 6; Reply RMTA 12 (citing Ex. 2075 ¶¶ 132–135).

In Opposition to the Revised Contingent Motion to Amend, Petitioner contends that the Specification of the ’575 patent does not support revised proposed substitute claim 20, specifically claim element 20j reciting “wherein, in the expanded position and the unexpanded position, no portion of the screw extends beyond the aperture in the proximal portion of the elongate expander and into the window of the elongate expander when viewed from a top view.” Opp. RMTA 24–25 (citing Ex. 1001, 6:61–67, Fig. 15). Additionally, Petitioner contends that the ’575 patent never describes “the set screw 1042 as causing the elongate expander to longitudinally translate, which is required [by] PO’s new claim amendments [to claim 27] . . . [and] never describes the set screw 1042 as being cannulated or having an internal passageway.” Opp. RMTA 25.

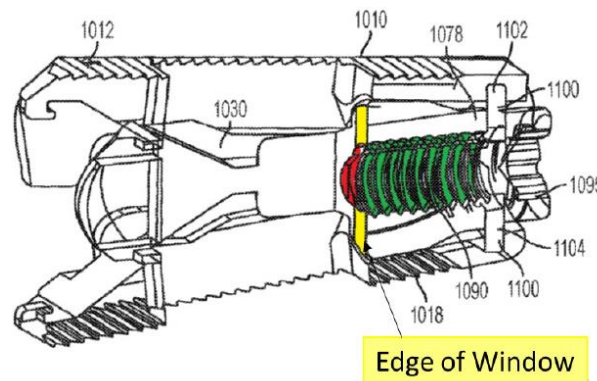
Based on the record before us, we agree with Petitioner that the '575 patent¹⁰ does not provide written descriptive support for the full scope of the contingent substitute claims. We address the lack of descriptive support for the limitations below:

1. *No Portion Of The Screw Extends . . . Into The Window Of The Elongate Expander*

Petitioner contends that:

Figures 5A–5B and 7–10 do not depict the actuating screw 1090 and, instead, illustrate the set screw 1042. The actuating screw 1090 and set screw 1042 are different components with different functions. The “set screw 1042” retains the expander in its final position, aids in containment of fusion material, and strengthens the proximal wall.

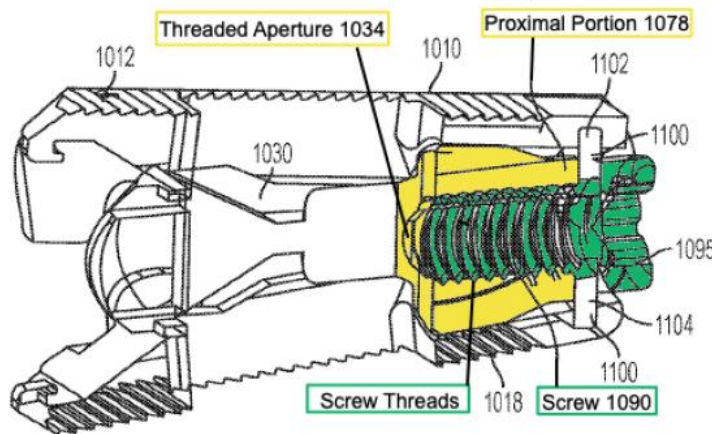
Opp. RMTA 24–25. Petitioner contends that the actuating screw extends into the window of the elongate expander when the device is in the expanded state. *See id.* at 24. Reproduced below is Figure 15 of the '575 patent as annotated by Petitioner.



¹⁰We discern no relevant differences between the Specification of the '575 patent and the '500 application.

Petitioner contends that “[t]he actuating screw 1090 is the only screw disclosed in the ’575 patent for longitudinally translating the elongate expander. (Ex. 1001, 6:61-67, Fig. 15.) Yet, the actuating screw extends into the window in the expanded position (*see red*).” Opp. RMTA 24. In other words, Petitioner contends that the tapered tip from the actuation screw extends into the window of the elongate expander as depicted by the red highlighting in the figure above. *See* Sur-reply RMTA 4.

Patent Owner asserts that Petitioner’s colored version is incorrect. Patent Owner provides their own colored version of Figure 15 of the ’575 patent, reproduced below:



According to Patent Owner, “Figure 15 shows the opposite because the screw threads (green) of screw 1090 are within the threaded aperture 1034 (yellow) of the proximal portion 1078 of the elongate expander but do not extend to the end of or beyond the end of the threaded aperture.” Reply RMTA 12 (citing Ex. 2075 ¶¶ 132–135); Ex. 2075 ¶ 135 (“An engineer . . . would understand that the portion colored red [in Petitioner’s annotated figure] is the threading in the end wall of the elongate expander in the cut-away viewpoint.”).

Petitioner responds:

Under PO's interpretation, the threaded aperture would be tapered. Not only is this unsupported by any figure in the '575 patent (see e.g., Fig. 10), but a threaded aperture would make it more difficult to pack bone growth material through the opening and would cause the screw to bind up in the expander. Petitioner's interpretation that the screw is tapered is more reasonable because the taper makes it easier to insert the screw into the implant opening.

Sur-reply 4.

None of the figures relied on by Patent Owner as allegedly providing support for the substitute contingent claim element 20j show an actuation screw engaged with the elongate expander. See RMTA 6 (citing Ex. 1001, Figs. 5A–5B, 7–10). Dr. Serhan's testimony as to the drawing interpretation of Petitioner's annotated Figure 15 of the '575 patent (Ex. 2075 ¶¶ 133–135) is entitled to little weight because it fails to explain how the Specification and file history support his position that the figure shows threading and not a cross sectional view of the device with an inserted screw. *Velder v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) ("It is within the discretion of the trier of fact to give each item of evidence such weight as it feels appropriate."); see 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."); cf. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) ("Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination."). Moreover, contrary to Dr. Serhan's unsupported assertions, the file history of the '500 application (see Ex. 2012, 15 (element 432)) as well as Dr. Robinson's declaration (see

Ex. 2026 ¶¶ 18, 25 (element 4)) support Petitioner’s assertion that screws used in implantable devices tend to have tapered tips for the ease of insertion into the device. *See* Sur-reply 4. Accordingly, we give Dr. Serhan’s unsupported, conclusory opinion no weight.

With respect to Figure 5B of the ’575 patent, the parties agree that this figure shows an unobstructed window. *See above* 2.C.3. What is not clear from the Specification, however, is that the expanded aligned window in Figure 5B shows the edge of the elongate expander window. In other words, the window of the elongate expander even in the expanded position can still be offset from the other windows, and therefore, you would not see the edge of the elongate expander window when viewed from the top. There is also no indication in the ’575 patent that Figure 5B is shown in the expanded position with an actuation screw inserted. Figures 7–10 also do not show the elongate expander with the actuation screw inserted. The ’575 patent, even when viewed in the light most favorable to Patent Owner, would at best provide motivation to create the largest internal cage cavity for inserting bone growth material, but this would merely render the limitation—that no portion of the screw extends into the window of the elongate expander—obvious which is insufficient for providing written descriptive support for the limitation. “A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations.” *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998).

Accordingly, we agree with Petitioner that the ’575 patent does not provide sufficient written descriptive support for the limitation that “no

portion of the screw extends beyond the aperture in the proximal portion of the elongate expander and into the window of the elongate expander when viewed from a top view” as recited in contingent substitute claims 20.

2. *Cannulated Set Screw*

The ’575 patent describes three types of screws: a set screw, a cap screw, and an actuation screw.

The set screw 1042, in one aspect, may be sized and shaped to retain the expander 1032 firmly within its final position, such that the expander 1032 will not retreat or otherwise “back out” unless purposely driven by a tool, also aiding in containment of the fusion material within the cage assembly and strengthening the proximal wall of the construct.

Ex. 1001, 5:39–45.

Either before or after placement of the bone fusion material, a cap or set screw 1042 may be inserted (using a drive rod 1068 or another tool inserted through the cannula 1062) into the proximal portion 1078 of the expander. The set screw 1042 helps contain the bone fusion material and also strengthens the proximal end wall of the cage body 1010.

Ex. 1001, 6:40–46.

In another aspect, a cap 1042 such as the cap screw . . . may be inserted into the proximal end of the body 1010. The cap 1042 helps contain the bone fusion material and also strengthens the proximal end wall of the cage body 1010.

Ex. 1001, 7:57–61.

In one aspect, the trailing end of the elongate expander is cannulated and has internal threads. The internal threads are configured to engage the external threads of an actuating screw 1090. The *actuating screw 1090* engages the proximal portion of the elongate expander.

Ex. 1001, 6:61–63 (emphasis added).

In another aspect, the cage body comprises a shoulder 1100 substantially adjacent the trailing end. In an exemplified aspect, the shoulder defines an orifice 1110 configured for receipt of the actuating screw 1090. The actuating screw comprises a head 1095 having a head diameter 1096 that is larger than the orifice diameter 1115.

Ex. 1001, 7:1–6.

Bone fusion material may be inserted into the one or more windows 1050 into the body 1010, and thereby into the proximity of the surrounding bony structures, in order to further secure the cage assembly 1000 in place. *In the aspect having a cannulated actuation screw, the bone fusion material may be inserted post expansion via the internal passageway of the actuating screw.*

Ex. 1001, 7:50–56 (emphasis added).

We agree with Petitioner that the '575 patent does not disclose the use of the set screw as being cannulated. Here, the '575 patent describes the use of a “set screw” and “cap screw” interchangeably. Indeed, the '575 patent identifies element 1042 as either a set screw or a cap screw. The '575 patent describes that “[t]he set screw 1042 helps contain the bone fusion material” the same function can be achieved with a cap screw. Ex. 1001, 6:40–46, *see id.* 7:57–61 (“cap 1042 such as the cap screw The cap 1042 helps contain the bone fusion material.”). The “set screw 1042 may be inserted . . . into the proximal portion 1078 of the expander. The set screw 1042 helps contain the bone fusion material and also strengthens the proximal end wall of the cage body 1010.” Ex. 1001, 6:40–46. Thus, the Specification of the '575 patent describes that the set screw can interact with the elongate expander and functions to strengthen the device as well as contain the bone

fusion material within the device. However, the '575 patent does not disclose that the set screw is cannulated.

The '575 patent describes that the actuation screw may be cannulated and that the use of the “cannulated actuation screw, [allows] the bone fusion material may be inserted post expansion via the internal passageway of the actuating screw.” Ex. 1001, 7:50–56. The '575 patent is clear that the cap screw or set screw is different from the actuation screw and therefore not interchangeable.

Accordingly, we agree with Petitioner that the '575 patent does not provide written descriptive support for a “cannulated set screw” as recited in contingent substitute claim 27.

3. Set Screw For Longitudinal Translation

We agree with Petitioner that the '575 patent does not disclose the use of the set screw for longitudinal translation of the elongate expander as recited in contingent substitute claim 27. This function is assigned to the actuation screw in the '575 patent. Specifically, the '575 patent explains “[t]he actuating screw 1090 engages the proximal portion of the elongate expander.” Ex. 1001, 6:61–63. The '575 patent explains that by rotating the actuation screw 1090 and engaging in the elongate expander causes the cage to expand or collapse.

The internal threads are configured to engage the external threads of an actuating screw 1090. The actuating screw 1090 engages the proximal portion of the elongate expander. Rotation of the actuating screw in a first direction moves the elongate expander proximally and rotation of the actuating screw in a second direction moves the elongate expander distally.

. . . rotating the actuating screw in the first direction until the

cage body is in the expanded position sandwiches at least a portion of the shoulder between portions of the screw head and the proximal portion of the elongate expander. This action substantially locks the expander and the upper and lower portions of the cage body into position.

Ex. 1001, 6:61–7:14.

Therefore, the '575 patent describes the interaction between the actuating screw and the elongate expander, but does not describe a “set screw” for longitudinally translating the elongate expander.

Accordingly, we agree with Petitioner that the Specification of '575 patent does not provide written descriptive support for the use of a set screw for longitudinal translation of the elongate expander as in contingent substitute claim 27.

4. *Conclusion*

Based on the foregoing, Patent Owner has not satisfied the statutory and regulatory prohibition against introducing new matter in the proposed substitute claims. 35 U.S.C. § 326(d)(3); 37 C.F.R. § 42.221(a)(2)(ii). On that basis, we deny Patent Owner's Revised Contingent Motion to Amend. Accordingly, we do not reach the unpatentability arguments Petitioner raises with regard to the proposed substitute claims.

IV MOTION TO EXCLUDE

The party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence (“FRE”). *See* 37 C.F.R. §§ 42.20(c), 42.62(a) (2019). In a post grant review proceeding, where we both decide admissibility and serve as the fact-finder, we are well-positioned to determine and assign appropriate weight to

evidence presented, and we recognize that a complete record of the evidence is preferable to facilitate public access as well as appellate review.

Patent Owner filed a Motion to Exclude and requests that the entirety of Mr. Culbert’s Declaration, or at least paragraphs 35–230 be excluded. *See* MTE 11. Patent Owner asserts that Mr. Culbert’s Declaration is devoid of any independent analysis and merely parrots Petitioner’s arguments in the Petition as an essentially verbatim duplication, and should be excluded as irrelevant and lacking probative value (*see* MTE 1–9 (citing FRE 402, 403); *see* Reply MTE 2–4); and that Mr. Culbert’s Declaration should be excluded because it is not based on sufficient facts or data (MTE 9–11(citing FRE 702, 703); Reply MTE 4–5).

Petitioner opposes asserting that Mr. Culbert was actively involved in the preparation and drafting of his declaration. MTE Opp. 1 (citing Ex. 2042, 11:8–17, 12:3–8, 12:19–22). Petitioner contends that Patent Owner’s allegations with respect to Mr. Culbert’s Declaration address the weight we should give the testimony evidence, but that should not be a basis for excluding the declaration. *See* MTE Opp. 5 (citing CTPG, 79 (“A motion to exclude is not a vehicle for addressing the weight to be given evidence – arguments regarding weigh should appear only in the merits documents.”); *Fox Factory, Inc. v. SRAM, LLC*, IPR2016-01876, 2018 WL 1633754, at 20 (PTAB Apr. 2, 2018) (37 C.F.R. § 42.65(a))).

We agree with Petitioner that Patent Owner’s argument fails to provide any basis for excluding Mr. Culbert’s Declaration under Federal Rules of Evidence 402. Federal Rule of Evidence 401 provides that evidence is relevant if it “has any tendency to make a fact more or less probable than it would be without the evidence” and “the fact is of consequence in

determining the action.” FRE 401; FRE 402 (“Relevant evidence is admissible”). Courts have characterized the relevance threshold as being “very low.” *United States v. White*, 692 F.3d 235, 246 (2nd Cir. 2012) (quoting *United States v. Al-Moayad*, 545 F.3d 139, 176 (2nd Cir. 2008)). We find that Exhibit 1003 easily clears the very low threshold of relevance, and agree with Petitioner that Patent Owner’s arguments go to the weight we should give Mr. Culbert’s testimony, not its admissibility. See *Microfinancial, Inc. v. Premier Holidays Int’l.*, 385 F.3d 72, 81 (1st Cir. 2004) (“When the factual underpinning of an expert’s opinion is weak, it is a matter affecting the weight and credibility of the testimony—a question to be resolved by the [factfinder].”).

Patent Owner’s argument that Federal Rule of Evidence 403 compels exclusion because Mr. Culbert did not perform an independent analysis of the technical merit of the challenges, is unavailing. MTE 4–9; see Reply MTE 2–4. Rule 403 has limited applicability, if any, to bench trials like this proceeding. See, e.g., *Schultz v. Butcher III*, 24 F.3d 626, 632 (4th Cir/ 1994) (holding that “in the context of a bench trial, evidence should not be excluded under 403” because the court can “hear relevant evidence, weigh its probative value and reject any improper inferences”). In the end, Patent Owner’s arguments simply go to the weight the evidence should be given and not its admissibility.

Patent Owner’s motion that Federal Rule of Evidence 703 compels exclusion is also unavailing. Whether Mr. Culbert’s opinion is conclusory or is not adequately based on objective evidence goes to the weight we should accord to his testimony. MTE 10–11 (“Mr. Culbert merely provides conclusory statements void of analysis – which are parroted in the Petition –

therefore failing to explain the basis for his testimony.”). It is within our discretion to determine the appropriate weight to be accorded to the evidence presented, including the weight accorded to expert opinion, based on the disclosure of the underlying facts or data upon which the opinion is based. Our discretion includes determining whether the expert testimony is the product of reliable principles and methods and whether the expert has reliably applied the principles and methods to the facts of the case. As appropriate, we have explained above the weight that we accord the allegedly objectionable testimony by Mr. Culbert. Thus, we deny Patent Owner’s motion to exclude Mr. Culbert’s Declaration.

For the reason discussed above, we deny Patent Owner’s Motion to Exclude as it applies to Exhibit 1003.

V. MOTION TO STRIKE

Petitioner seeks to strike Patent Owner’s Exhibit 2070 which is new evidence and associated “new argument” that “Weiman’s Figure 67 is not prior art.” MTS 1; see Reply MTS 2. Because we neither rely on the objected-to exhibit nor reach the grounds relying on the Weiman reference, we deny Petitioner’s motion to strike as moot.

VI. CONCLUSION¹¹

Based on the full record, we determine that Petitioner shows by a preponderance of the evidence that claims 1–7 of the '575 patent are unpatentable under 35 U.S.C. § 102 over Greenhalgh, and claims 8 and 9 are unpatentable under 35 U.S.C. § 103(a) in view of Greenhalgh or the combination of Greenhalgh and Lynn. Patent Owner's Revised Contingent Motion to Amend is denied as to revised proposed substitute claims 20–28. Our conclusions are summarized below.

Claims(s)	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–7	102(a)	Greenhalgh	1–7	
8, 9	103	Greenhalgh	8, 9	
8, 9	103	Greenhalgh, Lynn	8, 9	
8, 9	103 ¹²	Greenhalgh, Weiman		
1–9	102(a)	Weiman		

¹¹ We note that Patent Owner has filed Application No. 17/864,363 on July 13, 2022 which is as a broadening reissue application of U.S. Patent No. 10,709,575, the patent at issue in the present proceeding. Paper 46. We remind Patent Owner of its continuing obligation to notify the Board of any related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2). We draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. 84 Fed. Reg. 16,654 (Apr. 22, 2019).

¹² As we explain above, because we determine that claims 1–9 are unpatentable over Greenhalgh either alone or in combination with Lynn, we do not reach the merits of the other grounds of unpatentability raised by Petitioner that rely on the Weiman or Glerum reference.

1–9	103	Weiman		
1, 4–6, 8, 9	102(a)	Glerum		
8, 9	103	Glerum		
Overall Outcome			1–9	

We further conclude that Patent Owner has not satisfied its burden on a motion to amend, and Petitioner has demonstrated by a preponderance of the evidence that proposed substitute claims 20–28 lack written descriptive support. Thus, we deny the Revised Contingent Motion to Amend:

Motion to Amend Outcome	Claims
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	20–28
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	20–28
Substitute Claims: Not Reached	

VII. ORDER

In consideration of the foregoing, it is hereby

ORDERED that, pursuant to 35 U.S.C. § 328(a), Petitioner has shown by a preponderance of the evidence that claims 1–9 of the ’575 patent are unpatentable;

FURTHER ORDERED that Patent Owner’s Revised Contingent Motion to Amend is *denied* in as to revised proposed substitute claims 20–28;

FURTHER ORDERED that Patent Owner’s Motion to Exclude is *denied*;

FURTHER ORDERED that Petitioner’s Motion to Strike is *denied*; and

FURTHER ORDERED that parties to the proceeding seeking judicial review of this Final Written Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PGR2021-00050
Patent 10,709,575 B2

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