

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Solventum Corporation,
Petitioner

v.

Wound Healing Technologies Corp.,
Patent Owner

Case IPR2025-01042
Patent 10,639,404

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL OF
INSTITUTION UNDER 35 U.S.C. § 314(a)

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EXHIBIT LIST

Ex. No.	Description
2001	Petitioner's Answer in Western District of Texas litigation
2002	3M Corp. Press Release announcing purchase of KCI
2003	U.S. Patent Publication No. 2011/0301556; the PGPUB of U.S. Patent Application No. 13/152,446
2004	PCT Application No. PCT/US2013/074763
2005	Information Disclosure Statement filed in U.S. App. No. 14/104,630
2006	Declaration of Joel Weiss, Esq. and exhibits
2007	Argenta <i>et al.</i> , U.S. Pat. Pub. No. 2010/0121229
2008	International Search Report in PCT/US2013/074763
2009	U.S. Patent No. 9,833,363 to Robinson <i>et al.</i>
2010	Complaint filed in the Western District of Texas
2011	Argenta <i>et al.</i> , U.S. Patent No. 5,636,643
2012	Argenta <i>et al.</i> , U.S. Patent No. 5,645,081
2013	Argenta <i>et al.</i> , U.S. Patent No. 7,216,651
2014	Petitioner's Remarks filed in response to an Office Action during prosecution of the '363 Patent

Pursuant to the Acting Director’s March 26, 2025 “Interim Processes for PTAB Workload Management” Memorandum, Patent Owner Wound Healing Technologies Corporation (“WHT”) respectfully requests that the Director exercise her discretion to deny institution of Petitioner Solventum Corporation’s (“Petitioner”) Petition for *inter partes* review of U.S. Patent No. 10,639,404 (“IPR”). The grounds for discretionary denial are compelling and supported by the facts and the equities of the case. The Board should deny institution under 35 U.S.C § 314(a).

Table 1 below shows the ‘404 Patent documents, their respective references names and the relevant date for each.

Table 1. The ‘404 Patent documents for reference in Inter Partes Review (IPR)

Reference Number	Reference Name	Date
U.S. Provisional Patent Application No. 61/350,988	‘988 Prov. Application	June 3, 2010 (pre-American Inventors Act)
U.S. Patent Application No. 13/152,446	‘446 Application	June 3, 2011
U.S. Patent Publication No. 2011/0301556	‘556 Publication	December 8, 2011
U.S. Patent No. 10,639,404	‘404 Patent	May 5, 2020

I. INTRODUCTION

The Petition should be denied under § 314(a) for multiple reasons.

First, based on the public record, prior to filing the Petition, Petitioner was aware of the '404 Patent for more than 11 years. Over a decade ago, U.S. Publication No. 2011/0301556 (EX2003; the PGPUB of U.S. Patent Application No. 13/152,446 which later issued as the '404 patent; the "'556 Publication") was cited against Petitioner's¹ own Patent Cooperation Treaty application (EX2004; PCT Application No. PCT/US2013/074763).

Petitioner then cited the '556 Publication during prosecution of its own U.S. Patent Application (EX2005; Information Disclosure Statement filed in U.S. Patent Application No. 14/104,630). The '556 Publication was further discussed at length, through 2017, in the prosecution of the U.S. Patent Application No. 14/104,630.

¹ Solventum is a spinoff of 3M, which had previously purchased KCI. *See* EX2001, Answer to Complaint at paragraph 13, "Solventum admits that, with certain exceptions relating to liabilities not implicated by the Complaint, it has assumed all liabilities arising out of the business, operations, and activities of what was formerly 3M's HealthCare Business."; and *see* EX2002, 3M press release announcing purchase of KCI, available at investors.3m.com/financials/sec-filings/content/0001104659-19-026418/a19-9264_1ex99d1.htm (last accessed September 3, 2025).

Thereafter, the '446 application was involved in a public appeal² at the PTAB (EX1006 at 54-103) from 2017 to 2019. Finally, in 2020, the '404 Patent issued.

In January 2023, Patent Owner sent a letter to Petitioner predecessor 3M Corporation regarding the '404 Patent. (EX2006; Declaration of Joel Weiss, Esq. and exhibits therein) In its response letter to Patent Owner, Petitioner failed to challenge the validity of the '404 Patent. (*Id.*)

By 2025, following the eleven years Petitioner was aware of the '404 Patent, Patent Owner had settled expectations regarding the validity of the '404 Patent. The Patent Owner's settled expectations regarding the validity of the '404 Patent compel discretionary denial of the IPR.

Additionally, the Petition should be denied as it relies on the "same or substantially the same prior art or arguments previously ... presented to the Office," during the prosecution of the application (EX1006) from which the '404

² *Dabico Airport Solutions Inc. v. AXA Power APS*, IPR2025-00408, Paper 21 at *3 (PTAB Jun. 18, 2025) "...patent applications (after 18 months) and issued patents are almost always publicly available to provide notice to the public, other inventors, competitors, and commercial interests. 35 U.S.C. § 122. Interested parties may find published patents and patent applications using the Office's automated search systems as well as publicly available resources on the Internet. *See* 35 U.S.C. § 41(i). As such, actual notice of a patent or of possible infringement is not necessary to create settled expectations."

Patent issued, and the appeal (EX1006 at 55-60; PTAB Decision on Appeal) of same.

All three of Petitioner's grounds include Argenta 2008 (EX1004) as the primary reference. Patent Owner points out that the subject matter of Argenta 2008 is present in Argenta 2010 (EX2007), which was rigorously considered by the Examiner and the PTAB. Petitioner acknowledges that Argenta 2010 was considered but marginalizes Argenta 2010 by stating that "[a] different Argenta publication (Argenta 2010) related to an apparatus for *cardiac tissue modulation* was considered" while omitting the fact that Argenta 2010 discloses negative pressure wound treatment. *See* Petition at page 24 and section II(B)(3) below.

The PTAB, in fact, closely reviewed Argenta 2010 in its decision on Appeal, and concluded that the subject matter in the cited reference Argenta 2010 and a secondary reference, were insufficient to reject the issued claims. The PTAB reversed all the obviousness rejections in the appeal.³

Because the newly-cited art in the Petition does not add any relevant, non-cumulative subject matter, and because Petitioner's arguments are insufficient

³ Patent Owner notes that the subject matter of Petitioner's secondary Hu reference is also cumulative of references considered by the Examiner during prosecution.

– the PTAB should unquestionably reject, on the merits, the challenge to validity of the ‘404 Patent.’“

II. DISCRETIONARY DENIAL OF THE PETITION IS APPROPRIATE

Acting Director Coke Stewart’s March 26, 2025 Memorandum lists the following discretionary considerations for determining whether to deny a petition under 35 U.S.C. §§ 314(a) and 324(a):

- Settled expectations of the parties, such as the length of time the claims have been in force;
- Whether the PTAB or another forum has already adjudicated the validity or patentability of the challenged patent claims;
- The strength of the unpatentability challenge; and
- Any other considerations bearing on the Director’s discretion.

Each of these considerations warrants discretionary denial of the Petition as explained below.

A. Settled Expectations of the Parties Warrant Discretionary Denial.

“Settled expectations” as to the ‘404 Patent – with respect to Petitioner, Patent Owner, and the Office – individually and collectively warrant denial of the Petition.

**1. Settled Expectations as to Petitioner's Knowledge of the
'404 Patent**

Petitioner has indisputably known of the '446 Application/
'404 Patent for more than 11 years prior to filing its Petition. But the Petitioner
elected not to challenge its validity in the USPTO until filing the Petition.
Petitioner's inaction created significant settled expectations in Patent Owner's
favor as to the validity of the patent, warranting denial of the Petition. *See Nvidia
Corporation v. Neural AI, LLC*, IPR2025-00606, Paper 16 at 2-3 (Director Jul. 31,
2025) (discretionary denial warranted based on petitioner's prior knowledge of
patent owner's portfolio; "Petitioner had actual notice of the challenged patents
and Petitioner's failure to seek early review of the patents favors denial.").⁴

Specifically, on March 28, 2014, the '556 publication (PGPUB of the
application that issued as the '404 Patent) was cited in the Search Report for
Petitioner's PCT Application No. PCT/US2013/074763 (EX2008). Notably, the
'556 publication was cited to Petitioner as an "X" citation, ("a document of
particular relevance; the claimed invention cannot be considered novel or cannot

⁴ Notably, the Director denied the petition on the basis of the
petitioner's actual notice despite the challenged patent having "not been in force
for a significant period of time[.]" *Nvidia*, IPR2025-00606, Paper 16 at 2-3.

be considered to involve an inventive step when the document is taken alone.”).

(*Id.*)

Only three weeks later, on April 17, 2014, Petitioner cited the ‘556 publication in an Information Disclosure Statement (EX2005), during the prosecution of its own patent, U.S. Patent No. 9,833,363 (EX2009) (the ‘363 Patent). Petitioner’s prompt citation of the ‘556 publication during prosecution of its own patent reinforces Petitioner’s *actual* knowledge of its contents.

Despite having actual knowledge in 2014, Petitioner waited *over a decade* before filing (in June 2025) its Petition seeking review of the ‘404 Patent.⁵

As the Director has recognized in several recent decisions, Petitioner’s longstanding, well-documented knowledge of the ‘404 Patent weighs heavily in favor of discretionary denial. *See, e.g., Amazon.com, Inc., et al., v. Audio Pod IP, LLC*, IPR2025-00757 Paper 15 at 3 (Director Aug. 14, 2025) (granting discretionary denial because “[p]etitioner appears to have had notice of the challenged patents or patent family for a significant period of time.”); *Ericsson Inc. et al. v. Procomm International Pte. Ltd.*, IPR2024-01452, Paper 16 at 3 (Director Jun. 25, 2025) (granting discretionary denial when “Petitioner was aware of [the

⁵ This was also more than *five years* after the ‘404 Patent issued (in May 2020).

challenged patent] as early as 2013—having been brought to Petitioner’s attention in a Notice of References Cited during the prosecution of one of its own patents”); *iRhythm Technologies, Inc. v. Welch Allyn, Inc.* IPR2025-00363, Paper 10 at 3 (Director June 6, 2025) (granting discretionary denial where “Petitioner was aware of [challenged patent] as early as 2013—having cited the then-pending application that issued as the challenged patent in an Information Disclosure Statement Petitioner filed in its own patent application—settled expectations favor denial of institution.”).

Petitioner’s actual knowledge of the ‘404 Patent for over a decade – and its failure to seek review of the patent during that time – created settled expectations in favor of Patent Owner and warrant denial of the Petition. “Petitioner’s awareness of Patent Owner’s applications and failure to seek early review of the patents favors denial and outweighs [countervailing] considerations.” *iRhythm*, IPR2025-00363, Paper 10 at 3.

2. Settled Expectations as to Patent Owner due to the PTAB’s Prior Adjudication of Validity and Patentability

During prosecution of the ‘404 Patent, Patent Owner responded to three Office Actions. (*See* EX1006). Upon receipt of the fourth Office Action, Patent Owner appealed the remaining rejections of the claims to the Board. (*Id.*)

An *ex parte* appeal to the PTAB was instituted in **2017** and continued through **2019**. (EX1006 at 54-103). Notably, during the appeal, the PTAB specifically considered Argenta 2010 and Robinson. *Id.* at 55-60. In its final decision, the Board reversed the Examiner's obviousness rejections (*id.* at 55-60.), leading to the allowance and issuance (in 2020) of the '404 Patent.

The claims of the '404 Patent have been in force since **May 5, 2020**, more than five years before Petitioner filed the IPR.⁶

3. Settled Expectations as to Petitioner *and* Patent Owner

In early January **2023**, the undersigned sent a letter on behalf of Patent Owner regarding the '404 Patent. (*See* EX2006). Petitioner responded by claiming

⁶ The number of years a patent has been in force is not dispositive. *See, e.g., Webgroup Czech Republic A.S., et al. v. Dish Technologies LLC*, IPR2025-00467, Paper 14 at 2-3 (PTAB Jul. 16, 2025): Discretionary denial warranted even though challenged patents were not in force for a “significant period of time” (issued 2019-2023) because the validity of the patents was considered in prior proceedings: “...despite that the patents were issued relatively recently, they have already been the subject of multiple [PTAB] proceedings.... The Board has issued final written decisions addressing almost all of the claims challenged by Petitioner in these proceedings.... Petitioner does not provide persuasive reasoning why an inter partes review is an appropriate use of Board resources under these circumstances. In view of the number of prior proceedings involving the challenged patents and in the absence of a persuasive reason from Petitioner, these circumstances favor discretionary denial.”

not to infringe the '404 Patent, but Petitioner did not dispute the validity of the patent. (*Id.*)

Patent Owner then filed a district court action in the Western District of Texas in **November of 2024** to enforce the '404 Patent against Petitioner. (EX2010; Complaint). Some eight months later, Petitioner filed its Petition.

That is, even after Patent Owner reminded Petitioner of the '404 Patent in Jan. 2023 (EX2006), Petitioner waited *two-and-a-half years* before filing its Petition. Discretionary denial is therefore warranted because Petitioner "had notice of the challenged patents of patent family for a significant period of time." *See Audi Pod IP, LLC*, IPR 2025-0075 Paper 11 at 3.

The timeline and Table 2 below illustrate Petitioner's more than 11 years of knowledge of the '404 Patent before Petitioner filed the IPR. Timeline events in red directly relate to KCI's⁷ knowledge of the existence of the '446 application/'404 Patent.

⁷ See note 2, *supra*.

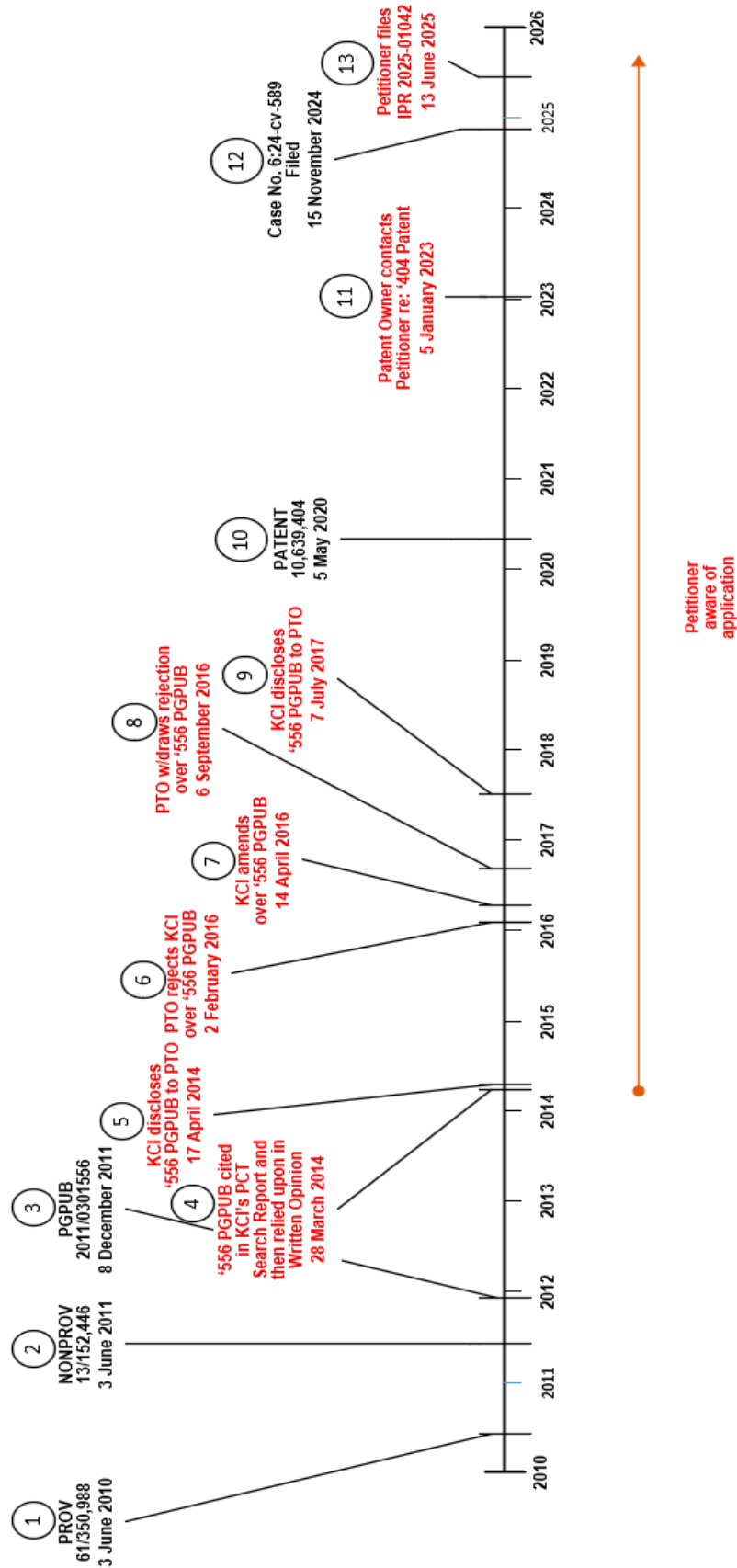


Table 2. Timeline Showing Petitioner's Knowledge of the '404 Patent

Event Number	Event Date	Event
1	6/3/2010	Patent Owner files priority application to '404 Patent (provisional)
2	6/3/2011	Patent Owner files non-provisional application
3	12/8/2011	Publication of the '446 application
4	3/28/2014	'556 Publication cited to Petitioner in Search Report for its PCT/US2013/074763, which eventually issued as U.S. Patent No. 9,833,363
5	4/17/2014	Petitioner discloses '556 Publication in IDS of its 363 Patent
6	2/2/2016	PTO cites '556 Publication to reject Petitioner's claims ('363 Patent)
7	4/14/2016	Petitioner amends its claims ('363 Patent) to avoid '556 Publication
8	9/6/2016	Based on Petitioner's amendments, PTO withdraws rejection over '556 Publication
9	7/7/2017	Examiner signs on IDS form creating record for face of '363 patent, said record showing consideration of '556 Publication
10	5/5/2020	Patent Owner's '404 Patent issues
11	1/5/2023	Patent Owner contacts Petitioner re: '404 Patent
12	11/15/2024	Patent Owner asserts '404 Patent against Petitioner in Western District of Texas litigation
13	6/13/2025	Petitioner files IPR seeking review of '404 Patent

B. The Petition Should Be Denied because the PTAB has Already Adjudicated the Validity or Patentability of the Challenged Patent Claims.

The Petition should be denied because the PTAB previously considered and confirmed the validity and patentability of the '404 patent's claims. *See* EX1006 at 55-60 (Decision on Appeal in *Ex Parte* Lichtenstein, Appeal 2018-002533 at *6, "The rejection of claims... under 35 U.S.C. § 103(a)... is reversed.").

Because "the PTAB... has already adjudicated the validity or patentability of the challenged patent claims[]" of the '404 Patent, discretionary denial is warranted.⁸ March 26, 2025 Memorandum at 2.

⁸ The Director has confirmed (across several recent decisions) that the consideration of a patent's validity in prior proceedings weighs heavily in favor of discretionary denial of a petition. *See, e.g., Intel Corporation v. Advanced Cluster Systems Inc.*, IPR2025-00794, Paper 13 at 2-3 (Director Aug. 14, 2025) (discretionary denial warranted when "the challenged patent was involved in two prior Board proceedings."); *Dentsply Sirona Inc. v. Osseo Imaging, LLC*, IPR2025-00771, Paper 8 at 2 (Director Jul. 31, 2025) (granting discretionary denial because "the challenged patents have already been upheld as not invalid in a district court proceeding, and the Federal Circuit affirmed that verdict.... It is not an efficient use of Board resources to consider the Petitions under these circumstances."); *Webgroup Czech Republic A.S., et al. v. Dish Technologies LLC*, IPR2025-00467, Paper 14 at 2-3 (Director Jul. 16, 2025) (discretionary denial warranted because challenged patents "have already been the subject of multiple [PTAB] proceedings.... Petitioner does not provide persuasive reasoning why an *inter partes* review is an appropriate use of Board resources under these circumstances. In view of the number of prior proceedings involving the challenged patents..., these circumstances favor discretionary denial.")

35 U.S.C. § 314(a) states that the Director may not authorize an inter partes review to be instituted unless the Petition demonstrates that, more likely than not, at least one of the claims challenged in the Petition is unpatentable. “In determining whether to institute a proceeding. . . the Director may take into account whether, and reject the Petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.”

Discretionary denial is further warranted because the Petition rehashes the substance of the Examiner's obviousness rejection. As noted above, the Board carefully considered and *reversed* this rejection in the *ex parte* appeal. EX1006 at 55-60 (Decision on Appeal). This is so because the Board's 2019 decision in the *ex parte* Appeal created “settled expectations” for Patent Owner as to the validity and patentability of the challenged claims, particularly with respect to the substance of the grounds for rejection now raised in the Petition.

Additionally (and as further detailed below), the Petition effectively seeks to “repackage” the substance of the Examiner's obviousness rejection (which the Board considered and reversed). This underscores the lack of “strength of the unpatentability challenge[,]” which further weighs in favor of denial. March 26, 2025 Memorandum at 2.

1. Petitioner’s Primary Reference, Argenta 2008, is Cumulative of Previously Considered Argenta References

Each of the Petition’s grounds for rejection relies principally on Argenta 2008.⁹ Two other Argenta applications and two Argenta patents were considered during the prosecution and *ex parte* Appeal of the ‘404 Patent. There is no relevant subject matter cited from Argenta 2008 that was not in the previously cited Argenta patents and applications.

The Argenta patents and applications, and their respective treatment by the Petition, are set forth in Table 3 below.

Table 3. Argenta Patents and Applications

Reference Number	Reference Name	Cited in . . .	Treatment by Petition
U.S. Publication No. 2008/0208147 (EX1004)	“Argenta 2008”	Petition	Primary Reference for All Counts
U.S. Publication No. 2010/0042021 (EX2007)	“Argenta 2010”	During Prosecution by Examiner, and considered by PTAB as Primary Reference in reversed rejections	Described in Petition as “an apparatus for cardiac tissue modulation”

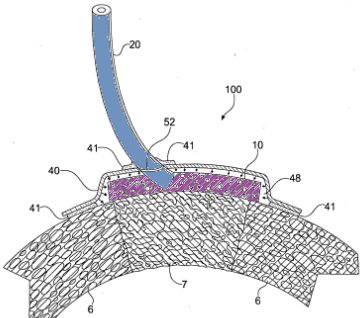
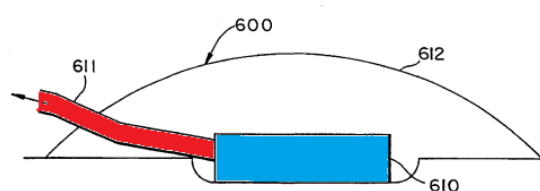
⁹ Though this brief refers to the referenced publication (US 2008/0208147) as “Argenta 2008” for clarity, the Petition refers to it as “Argenta.”

Reference Number	Reference Name	Cited in . . .	Treatment by Petition
U.S. Patent No. 5,636,643 (EX2011)	"Argenta '643"	During Prosecution, cited by Patent Owner; incorporated by reference in Argenta 2008	Omitted
U.S. Patent No. 5,645,081 (EX2012)	"Argenta '081"	During Prosecution, cited by Patent Owner; incorporated by reference in Argenta 2008	Omitted
U.S. Patent No. 7,216,651 (EX2013)	"Argenta '651"	During Prosecution, cited by Patent Owner	Omitted

Table 4 below shows that all portions of Argenta 2008 cited in the Petition with respect to exemplary independent claim 3 of the '404 Patent were already present in previously considered Argenta patents and publications. These Argenta references were considered by the Examiner during the prosecution of the '404 Patent and *appear on the face of the '404 Patent*.

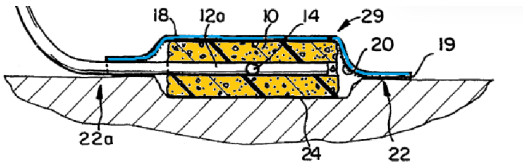
Table 4. Petition Primary Reference Argenta 2008 Cumulative in view of other cited Argenta Documents

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	References previously before the Office. Argenta 2010 was also directly considered by the PTAB:
A wound dressing comprising:	Petition, page 31, citing Argenta 2008, paras. 3 and 4.	To the extent Argenta 2008 discusses a wound cover, Argenta '643, as well as the other cited Argenta applications and patents,

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	References previously before the Office. Argenta 2010 was also directly considered by the PTAB:
		also discusses a wound cover, column 3, lines 1-2.
3(a) A wound-fluid drain for NPT wound treatment;	In addition to having an opening at the distal end 32, the tube 30 may be fenestrated along the portion of the tube 30 in communication with the enclosure under cover 10. <i>Petition, page 32, citing Argenta 2008 at para. 20.</i>	Argenta 2010 includes tube 20 (FIG. 2). "The tube 20 may have one or more fenestrations 23 in that portion of the tube 20 in contact with the porous material 10." Argenta '2010, Page 4, paragraph 38.  Fig. 2
3(b) A vacuum/drainage tube comprising a terminus;	Argenta discusses a vacuum/drain tube comprising a terminus. <i>Petition, page 34, citing Argenta 2008 at para. 20.</i>	Argenta '643 discusses: "a flexible hollow tube 611 inserted into the open cell foam section 610 and joined thereto with an adhesive and extending to attach at its opposite end with a Gast Vacuum Pump." Argenta '643 col. 5, lines 46-49.  FIG. 10

A schematic diagram of a vacuum pump system. A blue tube (12) connects a flask (32) to a device (19). The flask is connected to a pump (40) via a tube (34). The pump is connected to a vacuum source (38) via a tube (44). A control unit (42) is connected to the pump. The device (19) is shown in cross-section, with a tube (18) passing through it. The tube has a yellow section (14) and a red section (16). The device is mounted on a base (20) with a layer (22a) underneath.

FIG. 1

Claimed Element in Claim 3:	Petitioner's Reference (Argenta 2008):	References previously before the Office. Argenta 2010 was also directly considered by the PTAB:
3(d) Said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing transferring layer relative to the vapor sealant sheet; and	One of skill in the art would understand that Argenta's disclosure of a "self-adhesive" cover that binds to the screen and holds it in place to include adhesive in a central zone. <i>Petition, page 42.</i> (Bold portion is neither shown nor suggested by Argenta 2008.)	Argenta '643 discusses: "The wound cover for the reduced pressure appliance may be in the form of a gas impermeable covering sheet of flexible polymer material, such polyethylene, having an adhesive backing that provides the seal for securing the sheet over the wound site..." Argenta '643, col. 3, lines 52-56.  FIG. 1 (Bold portion is neither shown nor suggested by Argenta 2010 nor any of the cited references.)
3(e) a tube-exit-sealant component for mechanically maintaining the vacuum-drainage tube's placement relative to the fluid-absorbing/transferring layer.	See 3(d), above.	See 3(d), above.

In conclusion—all of the cited portions of Argenta 2008 are cumulative in view of the fact that the same prior art and arguments have already been considered, and rejected, by the PTAB. Because the '404 already overcame essentially the same rejection as advanced by the Petition, the Petition should be denied.

2. Secondary Reference Hu is Cumulative of Biggie.¹⁰

Hu, U.S. Patent Publication No. 2010/0042021 (EX1005) is cumulative of Biggie (U.S. Patent No. 7,520,872, EX1008), as set forth in Table 5 below. Because Biggie was considered during the prosecution of the '404 Patent and called out by the Examiner as relevant to the claims of the '404 Patent (*see* EX1006), Hu is cumulative. Because Hu is cumulative to references previously considered by the PTAB, all claims in the Petition based on Hu should be denied.

Notably, despite the Examiner's consideration of the patentability of the challenged claims in view of Biggie, the Board ultimately found the claims patentable. EX1006 at 55-60 (Decision on Appeal).

¹⁰ This argument will be explored in further detail in Patent Owner's Petition Response.

Table 5 – Secondary Reference Hu is Cumulative in View of Biggie

Claimed Element:	Petition cites Hu 2010/0042021 (Hu) as the secondary reference:	The citation in the Petition is cumulative of Biggie 7,520,872B2 (“Biggie”) previously considered by the Examiner and the PTAB:
A vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid absorbing layer;	Hu discusses a draping layer made of hydrocolloid material. <i>Petition at 41</i> . The Petition states (without basis) that, while the examiner considered Biggie (which also shows a hydrocolloid draping layer), she only considered an embodiment “in which <i>the (hydrocolloid) gel is covered by a protective cover.</i> ” <i>Petition at 28</i> .	The Petition fails to appreciate that Biggie included an embodiment without a protective cover. As such, Hu is cumulative of Biggie . Biggie, para. 54, states: In Fig. 4 , a side cutaway view of the preferred embodiment of fig. 3 is shown. In this figure, the pouch 1 is secured inside the wound cavity 11 by flexible gel 12. . . . A variety of commercially available gels can be used, such as hydro-colloids , silicones, or a gel, such as a hydrogel.

Below is a reproduction of Biggie’s FIGs. 4 and FIG. 5. Biggie FIG. 4 does not include a protective cover while Biggie FIG. 5 does include a protective cover. Contrary to Petitioner’s unfounded theory that the Examiner considered only FIG. 5, the record supports only a conclusion that the whole of Biggie was considered. Because the Examiner considered all of Biggie, Hu is cumulative.

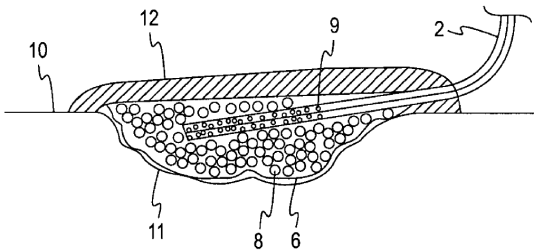


Fig. 4

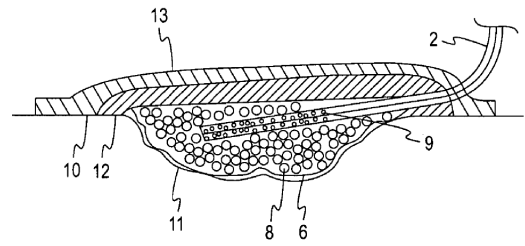


Fig. 5

In summary, Hu is cumulative of the disclosure in Biggie, especially with respect to Biggie FIG. 4, and the portion of the Biggie specification associated therewith.

Tables 4 and 5 indisputably show that the Petition cited the same prior art substance and arguments that were cited during prosecution of the '404 Patent. Importantly, the Petitioner fails to distinguish the substance of the Argenta prior art and Biggie considered in the prosecution of the '404 Patent, and before the PTAB, from Argenta 2008 and Hu, respectively.

3. The Petition Misstates the Significance of the Previously Considered Argenta Reference

There are yet "other considerations" that warrant discretionary denial of the Petition. March 26, 2025 Memorandum at 3. For example, as shown in the excerpt below, the Petition misleadingly suggests that the Argenta reference cited during the prosecution did not relate to negative pressure wound treatment.

C. Specific References Supporting Grounds of Unpatentability

1. U.S. Publication No. 2008/0208147 (EX1004) (“Argenta”)

Argenta published on August 28, 2008, is prior art under 35 U.S.C. § 102(b), and was not considered during prosecution of the '404 Patent. A different Argenta publication related to an apparatus for cardiac tissue modulation was considered. EX1006 at 114-115 (Jan. 26, 2017 non-final rejection at 8-9).

Petition at 24 (highlighting added). Petitioner's assertion is misleading on several grounds.

First, the Petition *misleads* regarding the subject matter of Argenta 2010 (the reference that was considered during prosecution and on appeal). As shown above, the Petition claims that Argenta 2010 (the “different Argenta publication” mentioned in the snippet above) is “related to an apparatus for ‘cardiac tissue modulation.’” However, Argenta 2010 is specifically related to negative pressure wound therapy. Petitioner's characterization misleadingly quotes part of Argenta 2010's title but omits a crucial phrase: “APPARATUS AND METHOD FOR CARDIAC TISSUE MODULATION **BY TOPICAL APPLICATION OF VACUUM** TO MINIMIZE CELL DEATH AND DAMAGE”. (emphasis added).

The Petition also omits that the PTAB considered Argenta 2010 during the *ex parte* Appeal of the '446 application. Rather, the Petition only cites

to a non-final rejection without mentioning that the Board (and the Examiner) focused on Argenta 2010.

The Petition misleadingly omits that Argenta 2010 was:

- 1) Directed to treating cardiac wounds with *negative pressure* (see, e.g., title of Argenta 2010, “APPARATUS AND METHOD FOR CARDIAC TISSUE MODULATION **BY TOPICAL APPLICATION OF VACUUM** TO MINIMIZE CELL DEATH AND DAMAGE”, (emphasis added));
- 2) Classified by the USPTO as relating to negative pressure wound treatment: US Cl. 601/6 Surgery, Kinisetherapy: Vacuum. (see below: USPTO Classifications 601/6); and

- 6 **Vacuum:**
This subclass is indented under subclass 1.
Subject matter having means for temporarily creating negative pressure upon a specific portion of the living body.

- 3) Carefully reviewed by the PTAB in its decision on appeal (EX1006 at 55-60).

Thus, the Petition, in its most prominent statement regarding the cumulative nature of its cited prior art, misleads the PTAB regarding the nature of the prior art previously considered by the Examiner and the PTAB.

Likewise, the Petition fails to mention that an additional three Argenta references dedicated to negative pressure wound treatment were considered during prosecution of the '404 Patent. Specifically, the Petition fails to mention that three other Argenta patents were considered during the prosecution of the '404 Patent – two of which *were incorporated by reference in 2008 Argenta*. In fact, the Petition implies (see snippet above) that no Argenta patents and publications relating to negative pressure wound treatment were cited during the '446 prosecution. Nothing could be further from the truth.

4. The Petition further Fails to Satisfy its Obligation to Point Out Errors in PTAB Adjudication of Validity

When a Petitioner presents prior art that was already substantively considered, the Petition is obligated to identify errors made by the Examiner. *See Ziegmann v. Stephens*, IPR2015-01860, Paper 13, at slip op. 10 (PTAB Sept. 6, 2017) (Ruschke, Boalick, Kim, DeFranco, Mayberry, JJ.) (“[W]hen a prior art reference presented in a Petition was already considered substantively by the Examiner, *the Petitioner has the initial burden to identify such errors made by the examiner with respect to that prior art reference*. Any factual finding made by the examiner and not contested by the Petitioner may be treated as undisputed fact for the purposes of evaluating Petitioner’s assertions *concerning examiner error under Sections 314(a) and 324(a)*.”) (citations omitted) (emphases added).

For the reasons above and others, the Petition fails to meet its initial burden with respect to previously considered art and arguments, and, therefore, the holding of the PTAB's Decision on Appeal (EX1006 at 55-60) reversing the obviousness rejections of the '446 application may be "treated as undisputed fact,"

Because, as explained above, Argenta 2008 and Hu are "the same or substantially the same prior art or arguments [as those] previously...presented to the Office," the decision by the Board in the *ex parte* appeal and by the Examiner should be treated as undisputed facts. Because Petitioner does not present any new, non-cumulative, references Patent Owner respectfully submits the Petition should be denied review under Sections 314(a).

C. The Petition should be Discretionally Denied because Petitioner is Unlikely to Prevail as the Petition Does Not Set Forth a *Prima Facie* Case of Obviousness.

Each of independent claims 1-3 of the '404 Patent recites, *inter alia*:

. . . a vapor sealant sheet formed from a hydrocolloid material, the vapor sealant sheet that overlies the fluid-absorbing/transferring layer, said vapor sealant sheet comprising an adhesive located over at least a central zone of a wound-facing surface of the vapor sealant sheet, the adhesive for adhering the vapor sealant sheet to the fluid-absorbing/transferring layer, said adhesive that mechanically maintains the placement and orientation of the fluid-absorbing layer relative to the vapor sealant sheet. . .

Emphasis added.

The Petitioner fails to cite any references that directly disclose or suggest the above-highlighted feature. In fact, the Petition omits direct treatment of this feature. *See* Petition at page 24.

The PTAB has already arrived at a finding of non-obviousness in view of similar, if not the same, prior art and arguments.

Moreover, para. 19 of Argenta 2008, in a singular embodiment, states that “[t]he screen 20 *is desirably cut and shaped to fit into and fill the wound 40.*” (See Argenta 2008, para. 0019.)

[0019] The screen 20 is desirably cut and shaped to fit into and fill the wound 40. As the wound 40 heals and becomes smaller in size, the size of the screen 20 may be decreased accordingly. The screen 20 may be held in place by contacting an adhesive coated under surface 12 of the cover 10 to assist in securing the screen 20 in a fixed position and to assist in the removal of the screen 20 when the cover 10 is removed. One particularly convenient configuration of cover 10 and screen 20 is the combination of a flexible self-adhesive polymer sheet or drape used in conjunction with an open-cell polymer foam.

The fluid-absorbing layer of the ‘404 Patent, on the other hand, has been placed relative to the vapor sealant sheet. Once placed relative to the vapor sealant sheet, such a fluid material absorbing/transferring layer cannot be cut, further shaped, or used to then fill a wound. *See* FIG. 9 from the ‘404 Patent below. Because of the claimed wound dressing architecture, the claimed fluid-

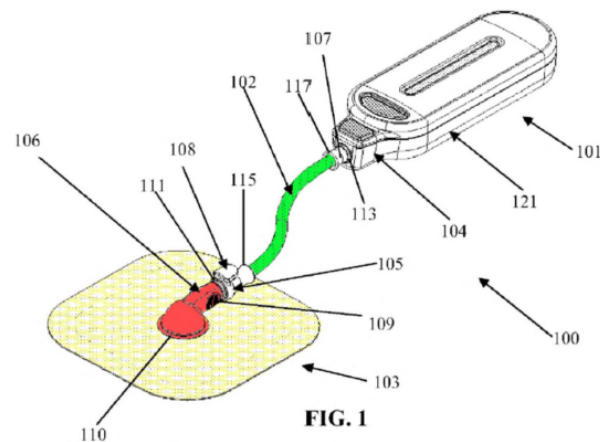
A European examiner, in the PCT International Search Report (EX2008) for Petitioner's PCT App. No. PCT/US2013/074763, characterizes the '556 publication as having – “an absorbent material *associated with* the sealing material.” (emphasis added).

In fact, it would require a change in principles of operation of Argenta 2008 to arrive at the claimed wound dressing, at least because Argenta 2008 discusses *a screen that can be cut, shaped to fit and used to fill the wound*. This Argenta principle of operation cannot show or suggest the claimed placement of the vapor sealant sheet that includes an adhesive that maintains a placement and orientation of the fluid-absorbing layer relative to the vapor sealant sheet. *See* elements 929 and 957 of FIG. 9 of the '404 Patent above. The placement and orientation of the fluid-absorbing layer relative to the vapor sealant sheet, as shown in FIG. 9, cannot be *cut, shaped and/or to fill the wound*. As such, Argenta 2008 cannot and, in its only relevant embodiment, does not, show or suggest a ***vapor sealant sheet that includes an adhesive that maintains a placement and orientation of the fluid-absorbing layer relative to the vapor sealant sheet.***

With respect to the foregoing principles of operation of Argenta 2008, Hu is limited to the same principles of operation as Argenta 2008 – i.e., that the wound is filled prior to application of a wound cover and that the wound filling is placed in the wound prior to mating it with the wound cover. See below, Petition

at page 27 stating, in pertinent part, the sealant layer in Hu, “can be used over top of a ‘contact layer matrix’ that is placed in the wound bed”. Such a mating would foreclose the possibility of a customization of the wound filling material. As such, Argenta 2008 and Hu are precluded from teaching an embodiment as claimed in the independent claims.

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EX1005 at Fig. 1 (color added). The sealant layer may be “made of a hydrocolloid material” (EX1005 ¶59) and can be used over top of a “contact layer matrix” that is placed in the wound bed to “distribute the reduced pressure more evenly through the wound bed” (EX1005 at ¶57) similar to the screen in Argenta’s device.

(highlights added). From the foregoing it is clear that, for this reason alone, both Argenta 2008 and Hu cannot be used to form an obviousness rejection with respect to the independent claims of the ‘404 Patent.

Argenta 2008 and Hu would require a change in their principles of operation to teach, *inter alia*, the above-quoted element. Accordingly,

Argenta 2008 neither shows nor suggests the claimed fluid-absorbing/transferring layer element.

Therefore, the Petition fails to show a *prima facie* case of obviousness and, as such, the unpatentability challenge cannot stand.

III. CONCLUSION

The PTAB should deny the Petition in view of the settled expectations of the Patent Owner. Specifically, Petitioner has known about the '446 Application/'404 Patent for more than 11 years. The '404 Patent issued over 5 years ago, and Patent Owner even sent a letter directly to Petitioner almost 3 years ago. Petitioner never challenged the validity of the '404 Patent until eight months after Patent Owner sued Petitioner in the Western District of Texas in 2024.

Additionally, the grounds in the Petition of rejecting the independent claims of the '404 Patent merely rehash the similar prior art references that were previously presented in the '404 *ex parte* Appeal to the Board (containing identical claim elements), and these same arguments were addressed in detail by the Board which allowed the '404 Patent.

The Petition also does not openly acknowledge the PTAB Decision on Appeal, identify additional subject matter advanced by new, non-cumulative prior

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art, much less point out specific errors in the PTAB's reasoning. Therefore, the IPR should be denied review under § 314(a).

For the foregoing reasons, Patent Owner respectfully submits that the Petition should be denied review under 35 U.S.C. § 314(a).

Respectfully submitted,

/Joel Weiss/

Joel Weiss

Reg. No. 44,398

Attorney for Patent Owner

Date: September 3, 2025

CERTIFICATE OF WORD COUNT

I, Joel Weiss, Esq., Attorney for Patent Owner, hereby certify, pursuant to Title 37 §42.24 of the Code of Federal Regulations, that the word count for this Petition is 5,677 words, which does not include the cover, the table or the certifications. This Petition therefore complies with the rule, which limits the Patent Owner's Request for Discretionary Denial to 14,000 words. I certify that this is the word count generated for this document in Microsoft® Word for Microsoft 365 MSO.

Respectfully submitted,

/Joel Weiss/

Joel Weiss

Reg. No. 44,398

Attorney for Patent Owner

Date: September 3, 2025

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the **PATENT
OWNER'S REQUEST FOR DISCRETIONARY DENIAL OF
INSTITUTION UNDER 35 U.S.C. § 314(a)** was served on the 3rd day of
September 2025, by email to counsel for Petitioner:

Daniel L. Moffett
Akin Gump Strauss Hauer & Feld, LLP
112 East Pecan, Suite 1010
San Antonio, TX 78205
T:210-281-7000
dmoffett@akingump.com

Respectfully submitted,

/Joel Weiss/

Joel Weiss, Esq. (lead counsel)
Reg. No. 44,398
Weiss & Arons LLP
Attorney for Patent Owner

63 South Main Street
Spring Valley, New York
T: 845-362-6100
jweiss@weissarons.com

Date: September 3, 2025