

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

Case No. IPR2023-01409

U.S. Patent No. 11,202,591

PATENT OWNER'S PRELIMINARY RESPONSE

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<i>Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH</i> , IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020)	passim
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<i>Microsoft Corp. v. Virtru Corp.</i> , IPR2023-00017, Paper 12 (P.T.A.B. May 17, 2023)	26
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TABLE OF EXHIBITS

Exhibit No.	Description
2001	PCT Publication No. WO 2005/046780

Patent Owner Abbott Diabetes Care Inc. submits this Preliminary Response to the Petition filed by DexCom, Inc. (“Petitioner”) requesting *inter partes* review of claims 1-30 (the “Challenged Claims”) of U.S. Pat. No. 11,202,591 (the “591 Patent”).

I. THE BOARD SHOULD DENY INSTITUTION UNDER § 325(d)

For purposes of this Preliminary Response, there is no need to step through all the reasons that the Petition fails substantively because it so clearly fails procedurally. Petitioner relies exclusively on prior art that was previously presented to the Office during prosecution, but fails to acknowledge, much less meet, its burden to demonstrate that the Examiner erred in a manner material to patentability of the Challenged Claims. Under the Board’s precedential decision in *Advanced Bionics* and the body of law that has followed, the Petition should be rejected on discretionary grounds.

In determining whether to deny institution under 35 U.S.C. § 325(d), the Board applies a two-part framework: “(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte*

GmbH, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential). “If a condition in the first part of the framework is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review.” *Id.* at 8-9. Part one of the *Advanced Bionics* framework indisputably is met here and Petitioner has not met its burden under part two. Therefore, the Board should exercise discretion not to institute *inter partes* review.

A. The First *Advanced Bionics* Factor Is Met Because All of Petitioner’s References Were Previously Presented to the Office

All five references relied on in the Petition’s eight Grounds are “the same or substantially the same art previously ... presented to the Office.” *Id.* at 8. “Previously presented art includes ... art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.” *Id.* at 7-8; *ABS Global, Inc. v. Cytonome/ST, LLC*, IPR2021-00306, Paper 13 at 10 (P.T.A.B. June 7, 2021) (finding the first *Advanced Bionics* condition indisputably met where the art relied upon in the petition was “submitted on an IDS during prosecution of the ’210 patent”); *Johnson & Johnson Surgical Vision, Inc. v. Alcon Inc.*, IPR2021-01069, Paper 16 at 14-15 (P.T.A.B. Dec. 10, 2021) (finding reference “cited in an IDS during prosecution” demonstrated that “the same or substantially the same art was previously presented”); *NXP USA, Inc. v. Impinj, Inc.*, IPR2020-00519, Paper 7 at 8 (P.T.A.B. Aug. 17, 2020) (same).

Grounds 1-8 in the Petition rely on various combinations of Stafford, Say, Shah, Brenneman, and Cote. *See* Pet. at 4. But each of these references or its materially identical counterpart was “previously presented” to the Office during prosecution of the 591 Patent.

Stafford, U.S. Publication No. 2008/0097246 (Ex. 1004), was previously presented to the Office in an Information Disclosure Statement (IDS) filed during prosecution of the 591 Patent. *See* Ex. 1002 at 80.

		US-2008/0083617	04-10-2008	Simpson, et al.	
		US-2008/0086042	04-10-2008	Brister, et al.	
		US-2008/0086273	04-10-2008	Shults, et al.	
		US-2008/0097246	04-24-2008	Stafford	
		US-2008/0108942	05-08-2008	Brister, et al.	
		US-2008/0114280	05-15-2008	Stafford	
		US-2008/0119707	05-22-2008	Stafford	

Id. (highlighting added). The Examiner certified that “all references” on the IDS were “considered except where lined through,” and he did not line through Stafford. *See id.* at 946. He then allowed the Challenged Claims over Stafford.

Say, U.S. Patent No. 6,175,752 (Ex. 1008), was previously presented to the Office in two IDSs filed during prosecution of the 591 Patent. *See id.* at 63, 71.

	249	6,122,351	09-19-2000	Schlueter Jr. et al.
	250	6,134,461	10-17-2000	Say et al.
	251	6,143,164	11-07-2000	Heller et al.
	252	6,175,752 B1	01-16-2001	Say et al.
	253	6,192,891 B1	02-27-2001	Gravel et al.
	254	6,338,790 B1	01-15-2002	Feldman et al.
	255	6,368,141 B1	04-09-2002	Van Antwerp et al.

Id. at 63 (highlighting added).

		US-6,121,611	09-19-2000	Lindsay, et al.	
		US-6,159,147	12-12-2000	Lichter, et al.	
		US-6,162,611	12-19-2000	Heller, et al.	
		US-6,175,752	01-16-2001	Say et al.	
		US-6,186,982	02-13-2001	Gross, et al.	
		US-6,200,265	03-13-2001	Walsh, et al.	
		US-6,212,416	04-03-2001	Ward, et al.	

Id. at 71 (highlighting added). For both IDSs, the Examiner certified that “all references [were] considered except where lined through,” and he did not line through Say. *See id.* at 929 (first IDS), 937 (second IDS). He then allowed the Challenged Claims over Say.

Shah, U.S. Publication No. 2007/0073129 (Ex. 1006), was previously presented to the Office in an IDS filed during prosecution of the 591 Patent. *See Ex. 1002 at 80.*

US PATENT DOCUMENTS					
Examiner Initials*	Cite No.	Document Number Number-Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2007/0073129	03-29-2007	Shah, et al.	
		US-2007/0078320	04-05-2007	Stafford	
		US-2007/0078321	04-05-2007	Mazza, et al.	
		US-2007/0078322	04-05-2007	Stafford	

Id. at 80 (highlighting added). The Examiner certified that “all references [were] considered” on the IDS “except where lined through,” and he did not line through Shah. *See id.* at 946. He then allowed the Challenged Claims over Shah.

Brenneman, PCT Publication No. WO 2008/115409 (Ex. 1040), was previously presented to the Office in an IDS filed during prosecution of the 591 Patent. *See Ex. 1002 at 52.*

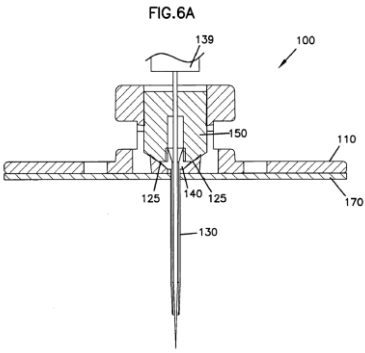
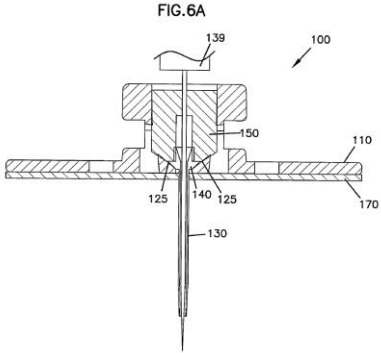
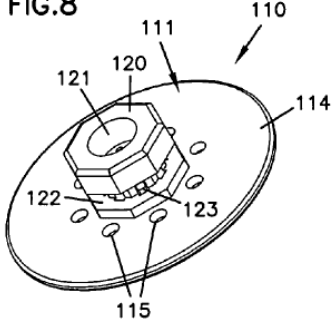
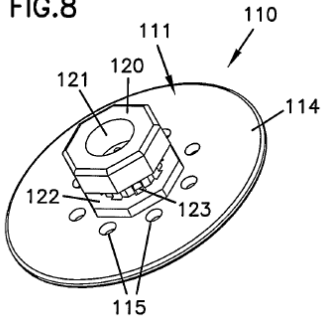
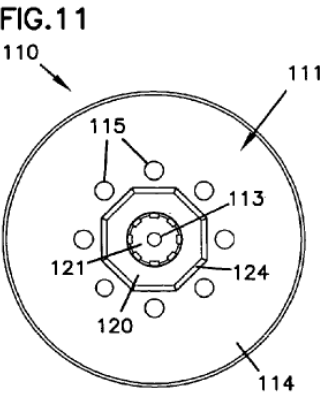
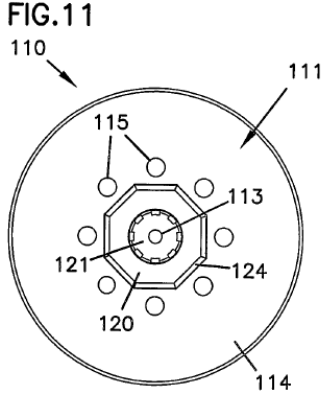
	10	WO 2006/086423 A2	08-17-2006	Therasense, Inc.	
	11	WO 2006/121921 A2	11-16-2006	Medtronic Minimed, Inc.	
	12	WO 2008/014792 A1	02-07-2008	Unomedical A/S	
	13	WO 2008/115409 A1	09-25-2008	Bayer Healthcare LLC	
	14	WO 2008/129532 A2	10-30-2008	Mor Research Applications Ltd.	
	15	WO 2008/157821 A1	12-24-2008	Abbott Diabetes Care, Inc.	

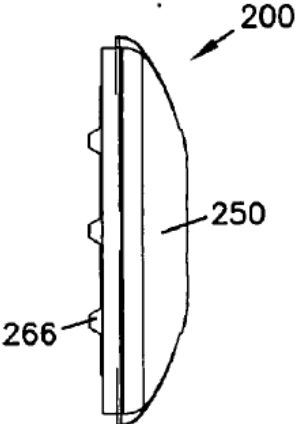
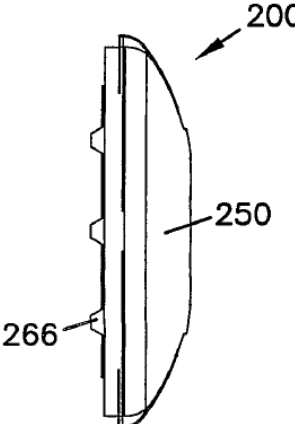
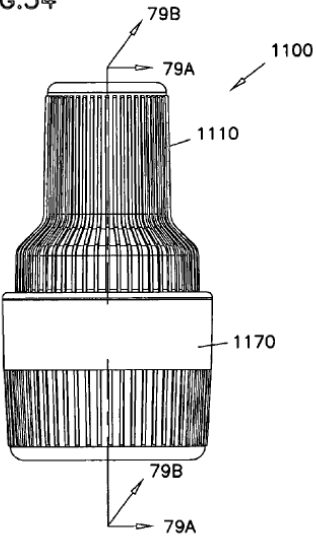
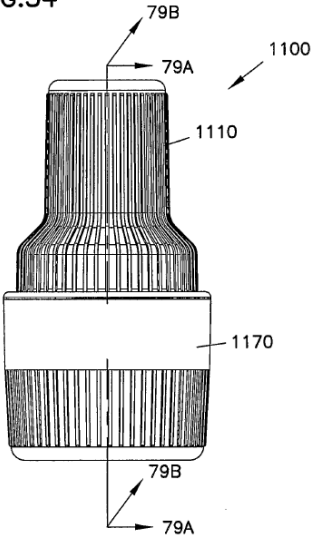
Id. at 52 (highlighting added). The Examiner certified that “all references [were] considered except where lined through,” and he did not line through Brenneman. *See id.* at 958. He then allowed the Challenged Claims over Brenneman.

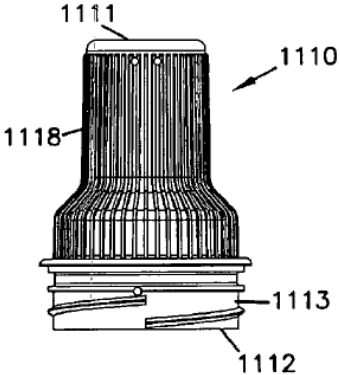
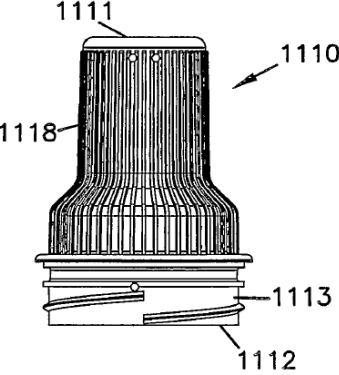
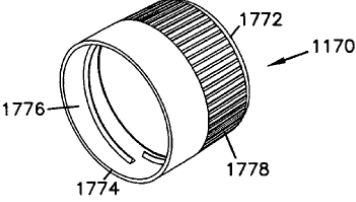
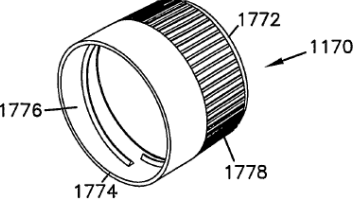
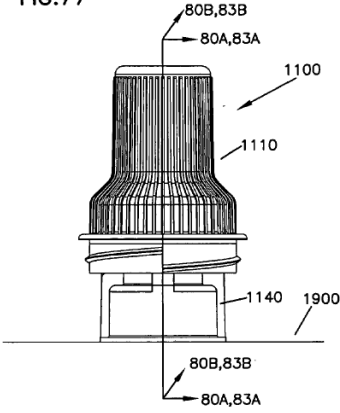
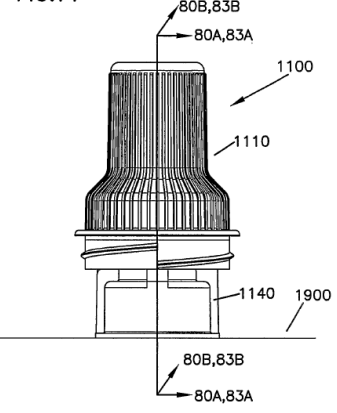
Lastly, Cote, U.S. Publication No. 2005/0101932 (Ex. 1005), was previously presented to the Office in an IDS as PCT Publication No. WO 2005/046780 (“Cote 780”). Cote 780 is a publication of PCT/US2004/030317, which claims priority to the version of Cote that Petitioner submitted. *See* Ex. 2001 at 1 (claiming priority to Serial No. 10/705,719); Ex. 1005 at 1 (identifying Serial No. as 10/705,719). The figures, specification, and even the claims are identical between Petitioner’s version of Cote (Ex. 1005) and Cote 780 that the Examiner considered (Ex. 2001). In particular, Cote 780 contains the same disclosure of Cote (Ex. 1005) that Petitioner relies on as shown in the table below:

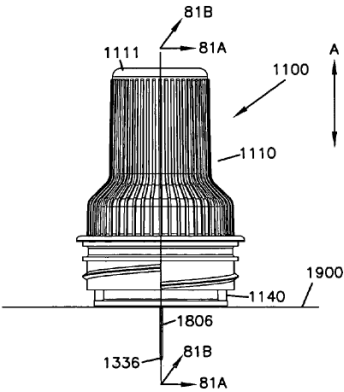
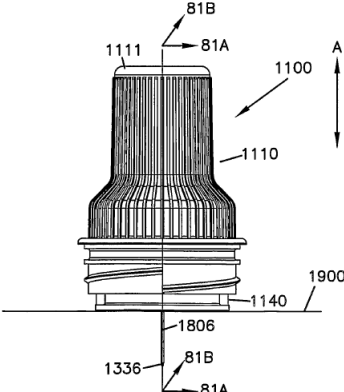
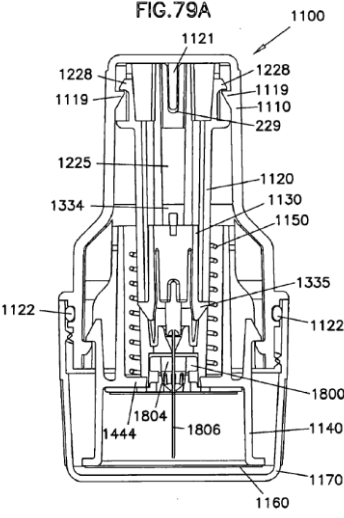
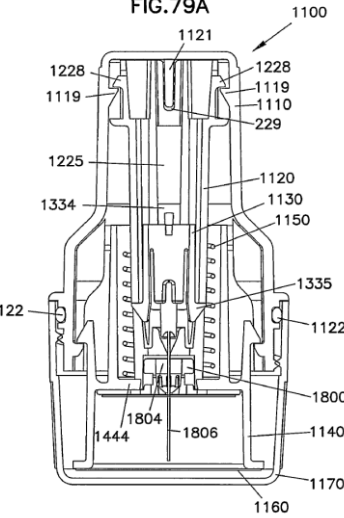
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
Ex. 1005 at ¶ 2	Ex. 2001 at 3:8-11
Ex. 1005 at ¶ 5	Ex. 2001 at 3:26-31
Ex. 1005 at ¶ 12	Ex. 2001 at 4:26-30
Ex. 1005 at ¶ 134	Ex. 2001 at 11:7-13
Ex. 1005 at ¶ 135	Ex. 2001 at 11:14-18
Ex. 1005 at ¶ 137	Ex. 2001 at 11:26-30
Ex. 1005 at ¶ 139	Ex. 2001 at 12:5-10

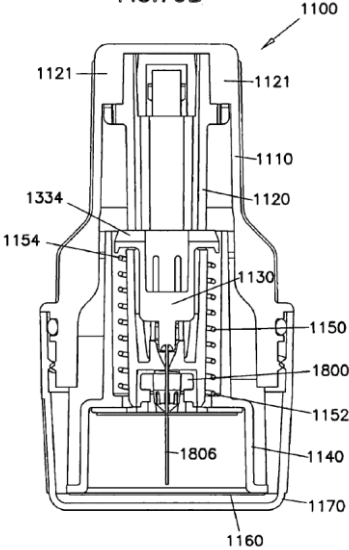
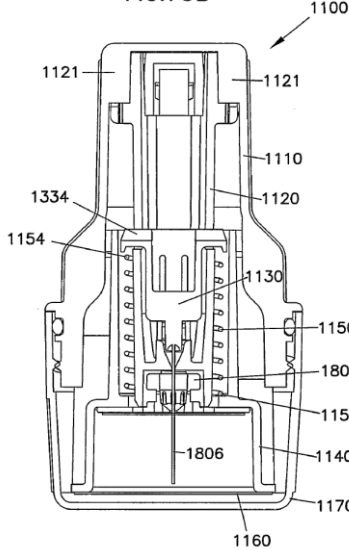
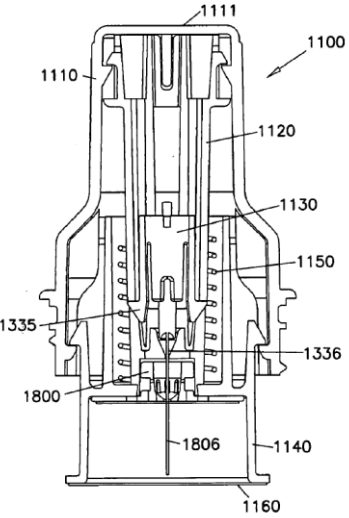
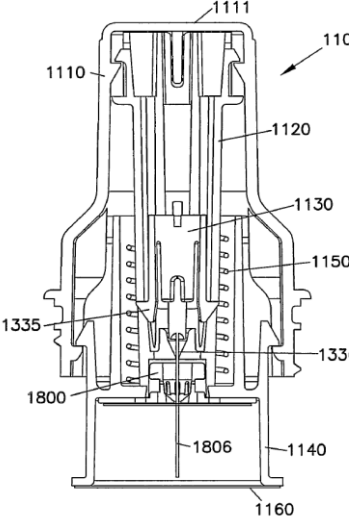
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
Ex. 1005 at ¶ 143	Ex. 2001 at 12:22-29
Ex. 1005 at ¶ 145	Ex. 2001 at 13:4-6
Ex. 1005 at ¶ 165	Ex. 2001 at 16:20-31
Ex. 1005 at ¶ 168	Ex. 2001 at 17:12-21
Ex. 1005 at ¶ 179	Ex. 2001 at 19:23-27
Ex. 1005 at ¶ 180	Ex. 2001 at 19:28-32
Ex. 1005 at ¶ 181	Ex. 2001 at 20:1-5
Ex. 1005 at ¶ 183	Ex. 2001 at 20:13-18
Ex. 1005 at ¶ 184	Ex. 2001 at 20:19-23
Ex. 1005 at ¶ 185	Ex. 2001 at 20:24-31
Ex. 1005 at ¶ 191	Ex. 2001 at 22:3-9
Ex. 1005 at ¶ 195	Ex. 2001 at 22:24-29
Ex. 1005 at ¶ 197	Ex. 2001 at 23:3-9
Ex. 1005 at ¶ 198	Ex. 2001 at 23:10-17
Ex. 1005 at ¶ 202	Ex. 2001 at 24:12-15
Ex. 1005 at ¶ 203	Ex. 2001 at 24:16-28
Ex. 1005 at ¶ 204	Ex. 2001 at 24:29-33
Ex. 1005 at ¶ 205	Ex. 2001 at 25:1-5
Ex. 1005 at ¶ 206	Ex. 2001 at 25:6-9
Ex. 1005 at ¶ 207	Ex. 2001 at 25:10-18
Ex. 1005 at ¶ 208	Ex. 2001 at 25:19-23
Ex. 1005 at ¶ 209	Ex. 2001 at 25:24-30
Ex. 1005 at ¶ 210	Ex. 2001 at 25:31 to 26:2
Ex. 1005 at ¶ 211	Ex. 2001 at 26:3-14
Ex. 1005 at ¶ 212	Ex. 2001 at 26:15-17
Ex. 1005 at ¶ 213	Ex. 2001 at 26:18-20
Ex. 1005 at ¶ 215	Ex. 2001 at 27:4-9
Ex. 1005 at ¶ 228	Ex. 2001 at 29:26-31
Ex. 1005 at ¶ 234	Ex. 2001 at 30:29-33
Ex. 1005 at ¶ 235	Ex. 2001 at 31:1-4
Ex. 1005 at ¶ 236	Ex. 2001 at 31:5-11
Ex. 1005 at ¶ 237	Ex. 2001 at 31:12-16

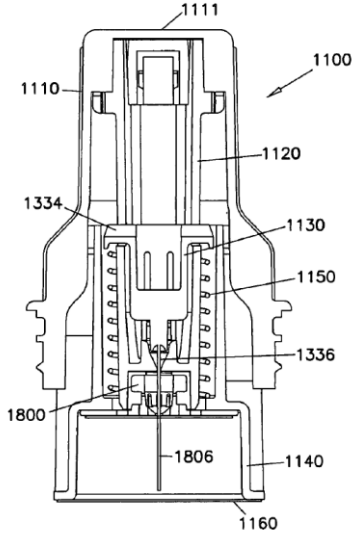
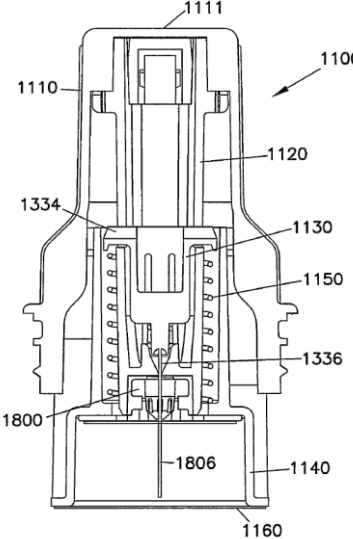
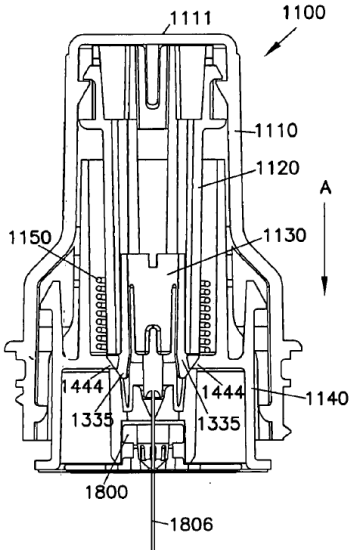
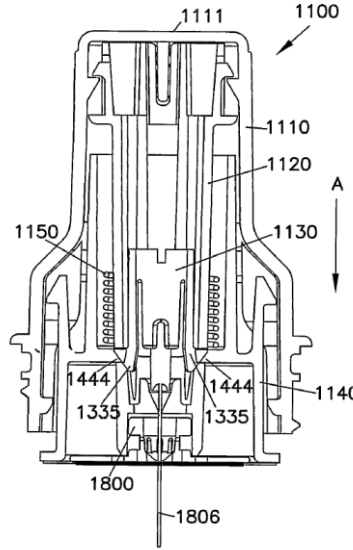
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
Ex. 1005 at ¶ 238	Ex. 2001 at 31:17-24
Ex. 1005 at ¶ 241	Ex. 2001 at 32:1-2
FIG.6A  Ex. 1005 at FIG. 6A	FIG.6A  Ex. 2001 at FIG. 6A
FIG.8  Ex. 1005 at FIG. 8	FIG.8  Ex. 2001 at FIG. 8
FIG.11  Ex. 1005 at FIG. 11	FIG.11  Ex. 2001 at FIG. 11

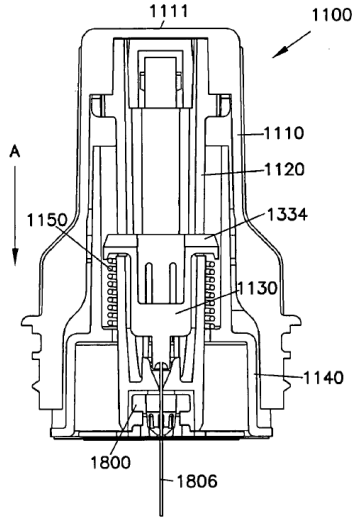
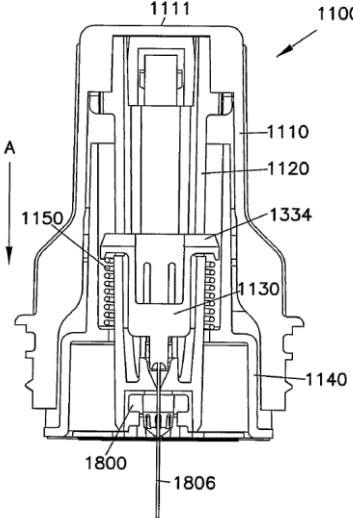
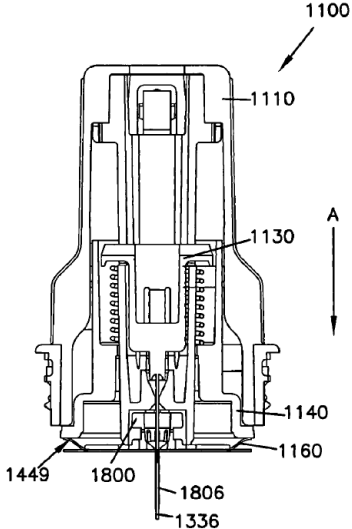
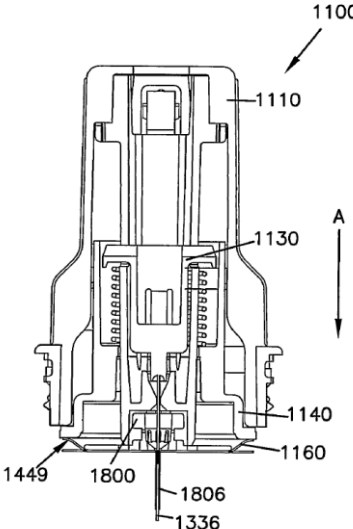
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.34  Ex. 1005 at FIG. 34	FIG.34  Ex. 2001 at FIG. 34
FIG.54  Ex. 1005 at FIG. 54	FIG.54  Ex. 2001 at FIG. 54

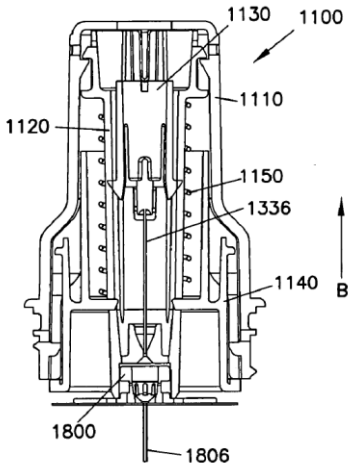
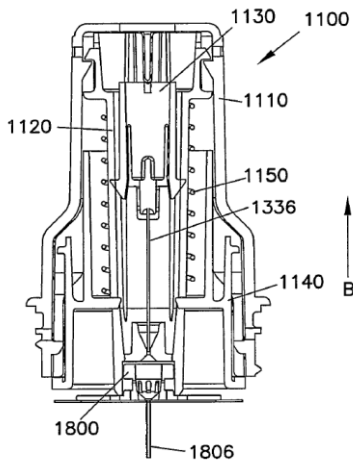
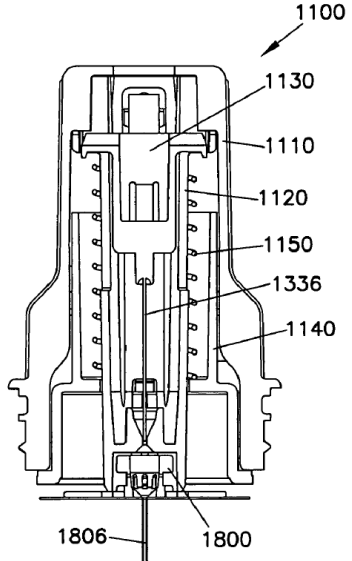
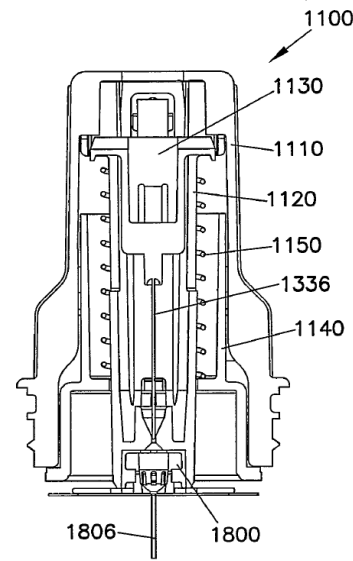
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.57  Ex. 1005 at FIG. 57	FIG.57  Ex. 2001 at FIG. 57
FIG.74  Ex. 1005 at FIG. 74	FIG.74  Ex. 2001 at FIG. 74
FIG.77  Ex. 1005 at FIG. 77	FIG.77  Ex. 2001 at FIG. 77

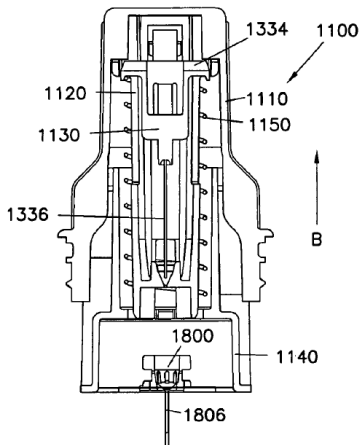
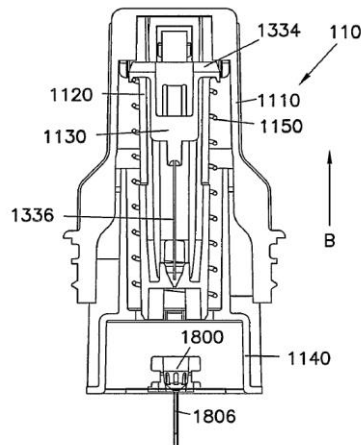
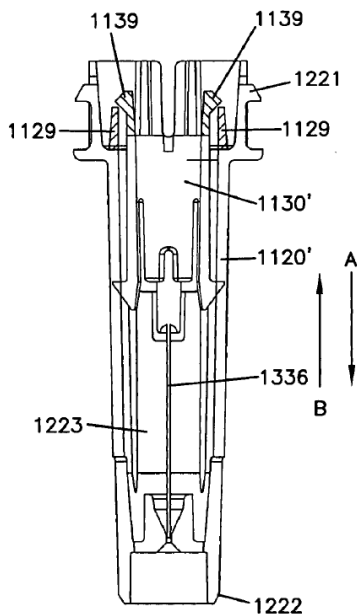
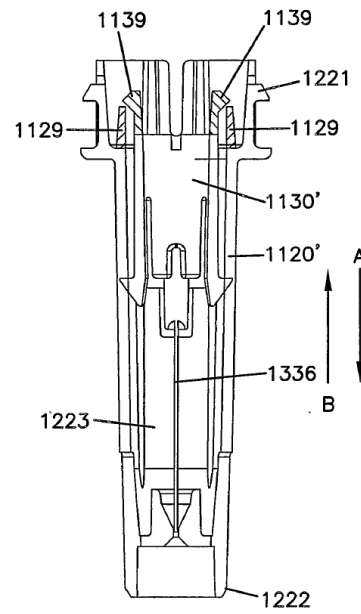
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.78  Ex. 1005 at FIG. 78	FIG.78  Ex. 2001 at FIG. 78
FIG.79A  Ex. 1005 at FIG. 79A	FIG.79A  Ex. 2001 at FIG. 79A

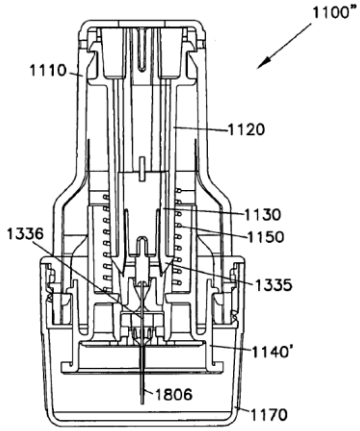
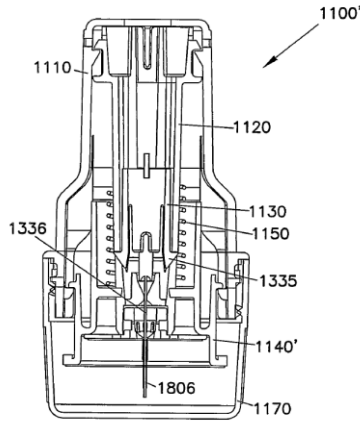
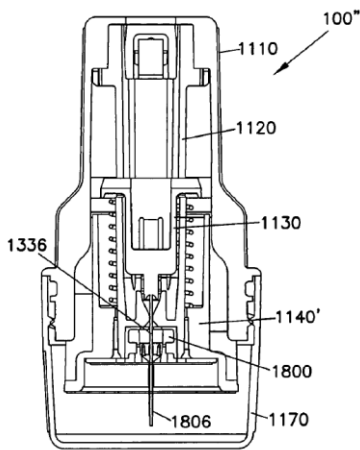
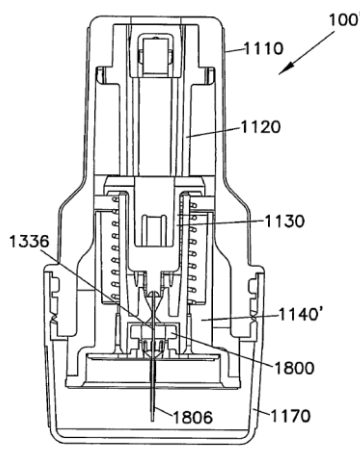
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.79B  Ex. 1005 at FIG. 79B	FIG.79B  Ex. 2001 at FIG. 79B
FIG. 80A  Ex. 1005 at FIG. 80A	FIG. 80A  Ex. 2001 at FIG. 80A

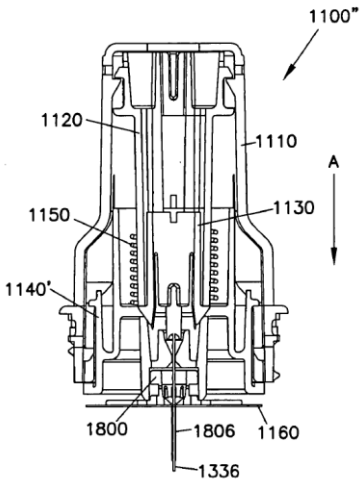
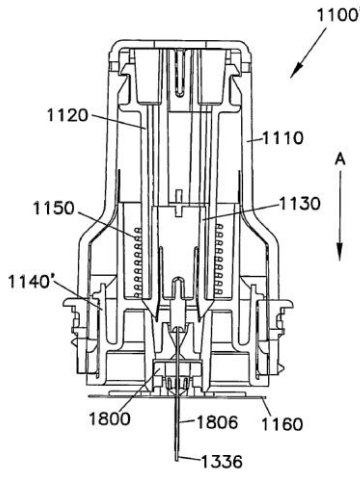
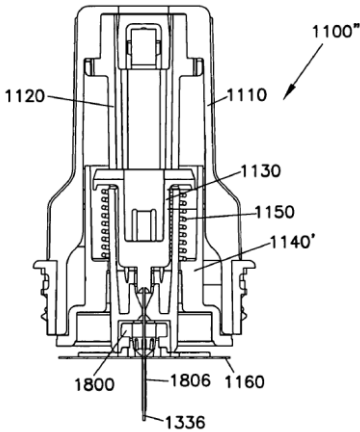
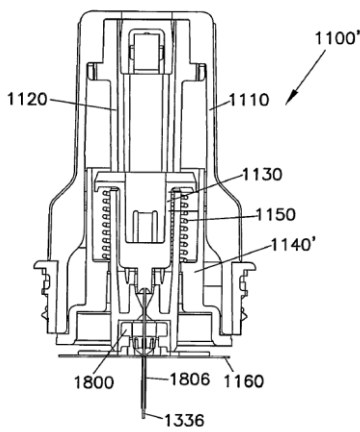
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.80B  Ex. 1005 at FIG. 80B	FIG.80B  Ex. 2001 at FIG. 80B
FIG.81A  Ex. 1005 at FIG. 81A	FIG.81A  Ex. 2001 at FIG. 81A

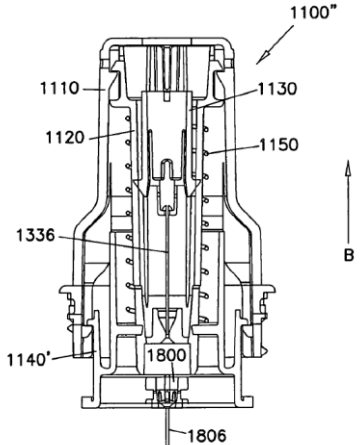
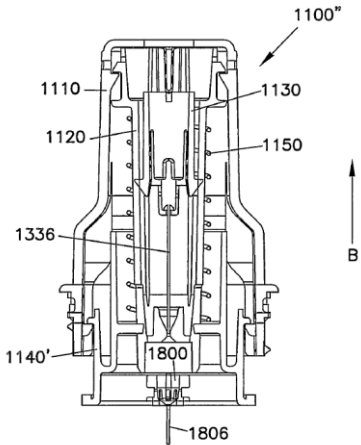
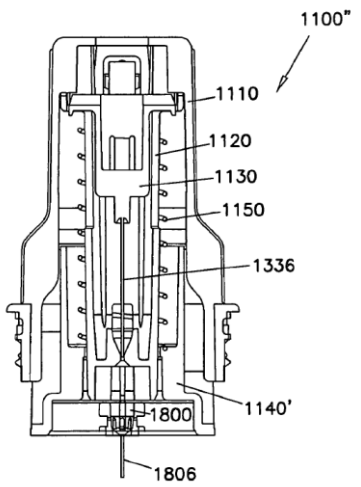
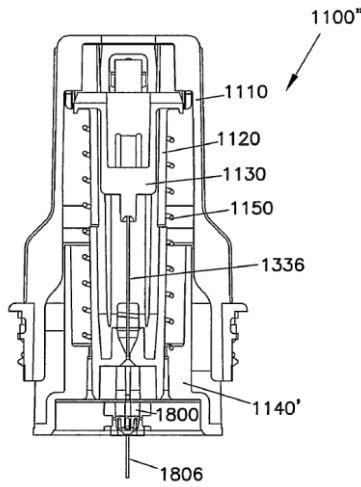
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.81B  Ex. 1005 at FIG. 81B	FIG.81B  Ex. 2001 at FIG. 81B
FIG.81C  Ex. 1005 at FIG. 81C	FIG.81C  Ex. 2001 at FIG. 81C

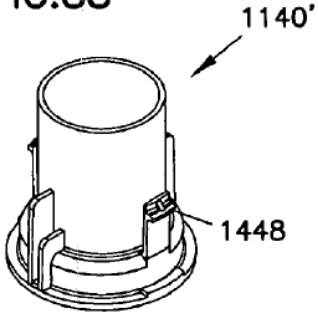
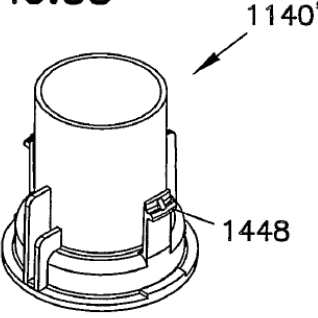
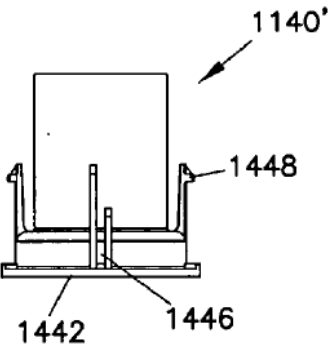
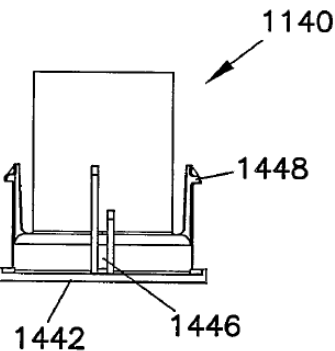
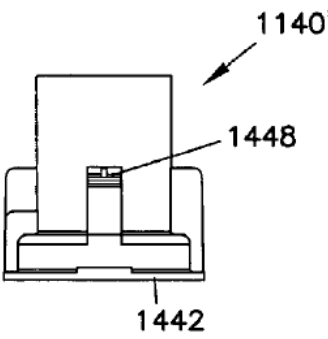
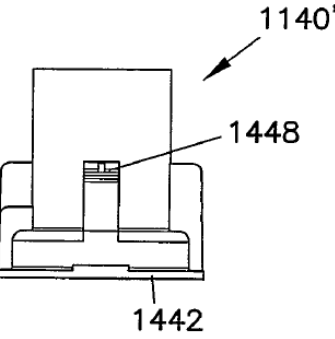
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.82A  Ex. 1005 at FIG. 82A	FIG.82A  Ex. 2001 at FIG. 82A
FIG.82B  Ex. 1005 at FIG. 82B	FIG.82B  Ex. 2001 at FIG. 82B

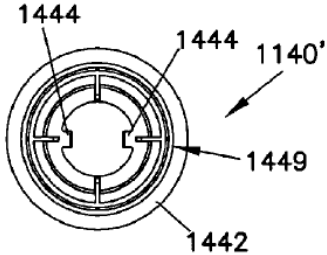
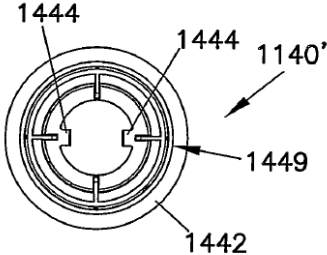
Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.83B  Ex. 1005 at FIG. 83B	FIG.83B  Ex. 2001 at FIG. 83B
FIG.84  Ex. 1005 at FIG. 84	FIG.84  Ex. 2001 at FIG. 84

Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.85A  Ex. 1005 at FIG. 85A	FIG.85A  Ex. 2001 at FIG. 85A
FIG.85B  Ex. 1005 at FIG. 85B	FIG.85B  Ex. 2001 at FIG. 85B

Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.86A  Ex. 1005 at FIG. 86A	FIG.86A  Ex. 2001 at FIG. 86A
FIG.86B  Ex. 1005 at FIG. 86B	FIG.86B  Ex. 2001 at FIG. 86B

Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.87A  Ex. 1005 at FIG. 87A	FIG.87A  Ex. 2001 at FIG. 87A
FIG.87B  Ex. 1005 at FIG. 87B	FIG.87B  Ex. 2001 at FIG. 87B

Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.88  Ex. 1005 at FIG. 88	FIG.88  Ex. 2001 at FIG. 88
FIG.89  Ex. 1005 at FIG. 89	FIG.89  Ex. 2001 at FIG. 89
FIG.90  Ex. 1005 at FIG. 90	FIG.90  Ex. 2001 at FIG. 90

Portions of Cote Cited in Petition	Cote 780 Considered by Examiner
FIG.91  Ex. 1005 at FIG. 91	FIG.91  Ex. 2001 at FIG. 91

Cote 780 was previously presented to the Office in an IDS filed during prosecution of the 591 Patent. *See* Ex. 1002 at 52.

Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		T ⁶
		Country ³ Number ⁴ Kind Code ⁵ (if known)				
	6	WO 03/026728 A2	04-03-2003	Maersk Medical A/S		
	7	WO 2004/098683 A1	11-18-2004	Novo Nordisk A/S		
	8	WO 2005/046780 A1	05-26-2005	Smith Medical MD, Inc.		
	9	WO 2005/123186 A1	12-29-2005	Medtronic, Inc.		
	10	WO 2006/086423 A2	08-17-2006	Therasense, Inc.		
	11	WO 2006/121921 A2	11-16-2006	Medtronic Minimed, Inc.		

Id. at 52 (highlighting added). Because Cote 780 contains the same disclosure as Cote (Ex. 1005), Cote is “‘substantially the same art’ that was previously presented to the Office.” *See Vital Connect, Inc. v. Bardy Diagnostics, Inc.*, IPR2023-00381, Paper 7 at 15-17 (P.T.A.B. July 11, 2023) (finding reference “Yang,” which was a continuation of “Yang Parent,” was previously presented to the Office because Yang Parent “is listed on an IDS and not lined through, indicating that the Examiner considered this reference,” “[t]he face of the ’743 patent also identifie[d] Yang Parent as a cited reference,” and the portions of Yang that Petitioner relied on were

“also present in Yang Parent”). The Examiner certified that “all references [were] considered except where lined through,” and he did not line through Cote 780. *See* Ex. 1002 at 958. He then allowed the Challenged Claims over Cote 780 (Ex. 1005).

In sum, ***all of the prior art*** relied on in Grounds 1-8 has already been presented to the Office. Indeed, each (or its substantially identical twin in the case of Cote) is listed in the “References Cited” section of the 591 Patent. *See* Ex. 1001 at 5 (Say), 9 (Shah), 10 (Stafford), 14 (Brenneman and Cote 780). The first *Advanced Bionics* factor is therefore indisputably met.

The Petition essentially admits that the first factor is met. It concedes that Stafford (Ex. 1004), Shah (Ex. 1006), and Say (Ex. 1008) “were each identified on an IDS.” Pet. at 5. Although the Petition contends that Brenneman (Ex. 1040) was not disclosed to the Office but that “US Publication No. 2010/0113897 to Brenneman” was (*id.*), Petitioner is clearly mistaken as shown above and evidenced by the file history. *See* Ex. 1002 at 52. Moreover, Petitioner’s identification of Brenneman’s counterpart, which is a national stage application of Petitioner’s version of Brenneman (Ex. 1040) and contains an identical disclosure, shows that Brenneman was previously presented to the Office at least twice during prosecution of the 591 Patent. And while Petitioner contends that Cote (Ex. 1005) was not disclosed to the Office, it admits that Cote 780 was, which has an identical disclosure to Petitioner’s version of Cote. *See Vital Connect*, IPR2023-00381, Paper 7 at 15-17

(finding parent listed on IDS with identical disclosure to prior art reference met part one of *Advanced Bionics*).

B. Petitioner Failed To Meet Its Burden To Show a Material Error Required by the Second *Advanced Bionics* Factor

Because the first *Advanced Bionics* condition is satisfied, it is Petitioner's burden to demonstrate how the Examiner allegedly erred. *Nespresso USA, Inc. v. K-Fee Sys. GmbH*, IPR2021-01223, Paper 9 at 29 (P.T.A.B. Jan. 18, 2022) ("Petitioner bears the burden of showing that the Office erred."). But the Petition addresses § 325(d) with only four sentences and does not even assert that, much less demonstrate how, the Office erred in a manner material to the patentability of the Challenged Claims. See Pet. at 5. This is reason alone to find that Petitioner failed to meet its burden under the second *Advanced Bionics* factor. *NXP*, IPR2020-00519, Paper 7 at 13 ("Petitioner does not identify any error in the Office's prior consideration of the Mandal '090 patent, which is substantially similar to the prior art asserted in the Petition. ... Thus, on this record, we determine that Petitioner does not demonstrate that the Office erred in a manner material to the patentability of the challenged claims."); *Nespresso*, IPR2021-01223, Paper 9 at 31 ("[T]he paucity of analysis provided by Petitioner in the Petition tips the scales in favor of a discretionary denial.").

Petitioner appreciated that its petition was vulnerable to discretionary denial under § 325(d) because it cited the statute and argued, albeit erroneously as shown

above, that two of its five references were not disclosed to the Office. *See* Pet. at 5. But Petitioner omitted any attempt to identify an alleged material error by the Examiner. Instead, Petitioner focused its only § 325(d) arguments on the incorrect proposition that the cited art was somehow not sufficiently presented to the Office such that the first part of *Advanced Bionics* is not met. In doing so, Petitioner makes factually unsupported and legally erroneous assumptions about the Examiner's state of mind.

The totality of Petitioner's § 325(d) arguments is:

Cote (EX1005) and Brenneman (EX1040) were neither cited nor discussed during prosecution of the '591 patent. Each provides express teachings on inserters for on-body units that were not considered by the Examiner.

While prior art references Stafford (EX1004), Shah (EX1006), and Say (EX1008), PCT publication WO2005/046780 to Cote, and US Publication No. 2010/0113897 to Brenneman were each identified on an IDS, nothing suggests the Examiner gave any of them more than a "[c]ursory consideration." Such minimal review "weighs against exercising discretion to deny under § 325(d)."

Pet. at 5 (citations omitted).

Petitioner, however, provides ***no evidence or analysis*** to support its argument that aspects of Cote and Brenneman were "not considered by the Examiner." To the contrary, the record evidence indisputably shows that the Examiner considered all

of the references relied on in the Petition, including Cote’s substantially identical counterpart and two versions of Brenneman. *See* Ex. 1002 at 929 (considering Say), 937 (considering Say again), 946 (considering Stafford and Shah), 958 (considering Cote and Brenneman); *see Vital Connect*, IPR2023-00381, Paper 7 at 16 (“Yang Parent is listed on an IDS and not lined through, indicating that the Examiner considered this reference.”).

Petitioner also provides ***no evidence or analysis*** to support its argument that “nothing suggests the Examiner gave any [of Petitioner’s five references] more than a ‘[c]ursory consideration.’” Pet. at 5. In fact, the record suggests the opposite. The IDSs in which Petitioner’s prior art was previously presented to the Office were submitted on April 2, 2021. *See* Ex. 1002 at 115. However, the Examiner certified that he considered Petitioner’s prior art (and other references) a ***full 7 months later***, on November 3, 2021. *See id.* at 929, 937, 946, 958. Thus, more than half a year passed between when Patent Owner presented Petitioner’s cited art (and other references) to the Office and when the Examiner certified that he considered all of the presented art. That is more than ample time for the Examiner to review the references. Petitioner’s assertion is therefore baseless and contradicted by the record evidence.

Moreover, Petitioner relies on *Intex Rec. Corp. v. Team Worldwide Corp.*, for the proposition that, when a prior art reference was previously disclosed to the Office

but not applied to the claims by the Examiner, it weighs against exercising discretion under § 325(d). *Intex Rec. Corp. v. Team Worldwide Corp.*, IPR2018-00871, Paper 14 at 13 (P.T.A.B. Sept. 14, 2018). That case, however, is non-precedential and predates *Advanced Bionics*. “The precedential decision in *Advanced Bionics* unambiguously instructs [that] ‘Previously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.’” *Nespresso*, IPR2021-01223, Paper 9 at 13 (criticizing Petitioner for relying on “non-precedential Board decisions, which predate *Advanced Bionics*, to argue that ‘the “mere submission of a reference in an IDS is insufficient for purposes of exercising discretion”’ to deny review under Section 325(d).”).

Indeed, other Board panels have expressly rejected reliance on the non-precedential *Intex* decision for the same reason that Petitioner relies on it. For example, in *Google v. Valtrus Innovations*, the petition cited a prior art reference in Grounds 6-8 (“Vea”) whose European counterpart was submitted in an IDS during prosecution of the challenged claims. *Google LLC v. Valtrus Innovations Ltd.*, IPR2022-01197, Paper 9 at 22 (P.T.A.B. Jan. 3, 2023). The Board found that this satisfied part one of *Advanced Bionics*. *Id.* As for the “material error” prong of *Advanced Bionics*, the Board criticized Petitioner for “providing a mere two sentence assertion regarding § 325(d) that ‘[n]one of the Ground’s references were before the

Office during the '809 Patent's prosecution. Discretionary denial is not warranted under § 325(d).” *Id.* at 23. This was insufficient to demonstrate material error and so the Board denied institution of Grounds 6-8 under § 325(d). *Id.*

The Board also noted that, during a conference call with the parties, Petitioner's counsel argued that “several Board cases stood for the proposition that ‘[t]he mere citation in an IDS is not enough to warrant a Section 325(d) denial.’” *Id.* at 24. The Board disagreed that any of these cases were instructive, one of which was the *Intex* case that Petitioner relies on here. *Id.* at 26. About *Intex*, the Board explained that “we find this particular decision inapposite for the simple reason that it predates our precedential *Advanced Bionics* decision establishing the two-part framework discussed *supra*.” *Id.* at 26. Thus, Petitioner's pre-*Advanced Bionics* arguments and cited case law are inapposite.

Petitioner also provides ***no evidence or analysis*** to support its argument that the Examiner conducted a “minimal review” of Petitioner's references. This is pure attorney argument lacking any support and should be summarily disregarded. See *Microsoft Corp. v. Virtru Corp.*, IPR2023-00017, Paper 12 at 10 (P.T.A.B. May 17, 2023) (rejecting Petitioner's attorney argument that did “not provide sufficient factual support”) (citing *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997) (“arguments of counsel cannot take the place of evidence lacking in the record”)). Moreover, as explained above, the only case that Petitioner relies on for

its § 325(d) arguments is the non-precedential *Intex* case, which *Advanced Bionics* has effectively overruled. See *Google*, IPR2022-01197, Paper 9 at 26.

Under *Advanced Bionics*, when the Petition relies on prior art that was previously presented to the Office, it is Petitioner who must affirmatively explain how the Examiner erred such that the Petition should be instituted. Furthermore, “[w]here ‘the record of the Office’s previous consideration of the art is not well developed or silent, then a petitioner may show the Office erred by overlooking something persuasive under’ *Becton, Dickinson* factors (e) and (f).” *Nespresso*, IPR2021-01223, Paper 9 at 29-30. In assessing factor (e), the Board “consider[s] whether Petitioner ‘point[s] out sufficiently how the examiner erred in its evaluation of the asserted prior art.’” *Id.* at 30. When considering factor (f), the Board “look[s] for some explanation of how or why ‘the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.’” *Id.* Petitioner addresses neither of these *Becton, Dickinson* factors, which is fatal to the Petition. *Id.*; see also *Sony Interactive Entm’t LLC v. Terminal Reality, Inc.*, IPR2020-00711, Paper 15 at 11-12 (P.T.A.B. Oct. 13, 2020) (denying institution under § 325(d) where Petitioner remained silent on *Becton, Dickinson* factors (e) and (f)).

The Board’s decision in *Vital Connect v. Bardy Diagnostics* denying institution under § 325(d) is directly on-point. Like here, all of the Petitioner’s prior

art (or substantially similar art) was previously presented to the Office via IDSs during prosecution. *Vital Connect*, IPR2023-00381, Paper 7 at 18. But also like here, Petitioner did not explain how the Examiner allegedly erred in a manner material to patentability of the challenged claims. *Id.* at 19. Instead, Petitioner was “silent on material error, even though its relied-upon references (or their substantially identical disclosures), were before the Office during examination.” *Id.* Consequently, the Board denied institution under § 325(d). *Id.* at 20.

In *Vital Connect*, the Board also refused to accept Petitioner’s boilerplate assertion that “the Petition presents grounds of unpatentability not previously considered and/or applied by the Examiner” as somehow demonstrating material error. *Id.* at 19. The Board explained:

But these statements, without any further analysis, cannot persuade us of material error. *Advanced Bionics* cautions that “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” Paper 6, 9. *Advanced Bionics* also explains the rationale for this rule: “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* Here, we defer to the Office’s previous consideration of the prior art of record because Petitioner’s statements (i.e., that the Petition presents grounds of unpatentability not previously considered and/or applied by the Examiner) do not “demonstrate[] that

the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics*, 8-9.

Vital Connect, IPR2023-00381, Paper 7 at 19-20. The Board should find the same here. The heading for Petitioner’s § 325(d) arguments is “No Examiner Addressed These Unpatentability Grounds.” Pet. at 5. As explained in *Vital Connect*, Board precedent dictates that this boilerplate statement does “not ‘demonstrate[] that the Office erred in a manner material to the patentability of the challenged claims.’” *Id.* at 20; *see also Google*, IPR2022-01197, Paper 9 at 22 (finding Petitioner’s “mere two sentence assertion regarding § 325(d)” insufficient to demonstrate material error). Nor do Petitioner’s other evidence- and analysis-free assertions explain how the Examiner allegedly erred. The Petition is simply silent on the material-error prong of *Advanced Bionics*.

Nor should the Board infer material error from Petitioner’s Grounds. The *Vital Connect* decision correctly explained that *Advanced Bionics* forecloses such an inference:

Moreover, while there are no “magic words” necessary to address material error, Petitioner’s alleged grounds of unpatentability cannot establish material error *per se* under our binding precedent. *See id.* (“If a condition in the first part of the framework is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute inter partes review.”). Otherwise, the reasonable likelihood standard of § 314(a) and the

second part of the *Advanced Bionics* framework (“material error”) would collapse into one.

Id. at 20.

In sum, Petitioner attempted to show that the first part of *Advanced Bionics* was not met, but failed. It then completely ignored the second part. Because each of Stafford, Say, Shah, Brenneman, and Cote’s substantially identical counterpart were previously presented to and considered by the Office, and because Petitioner failed to meet its burden under *Advanced Bionics*, the Board should exercise its discretion under § 325(d) and refuse to institute *inter partes* review. *Vital Connect*, IPR2023-00381, Paper 7 at 20.

II. PETITIONER SHOULD NOT BE PERMITTED A REPLY TO FURTHER ADDRESS § 325(d)

Patent Owner expects that Petitioner may ask to backfill its plainly deficient § 325(d) arguments by seeking a pre-institution reply to address, for the first time, the second prong of *Advanced Bionics*. The Board should not authorize such a reply because Petitioner has no good cause. This is not a case where Petitioner could not have foreseen Patent Owner’s arguments—it is the opposite situation. Petitioner has already addressed § 325(d) in the Petition (*see* Pet. at 5) and should not be afforded an opportunity to supplement months after filing. *Progenity, Inc. v. Natera, Inc.*, IPR2021-00266, Paper 7 at 5 (P.T.A.B. Apr. 1, 2021) (denying request for pre-

institution reply because Patent Owner’s § 325(d) arguments were “foreseeable” and “could have been comprehensively addressed by Petitioner in the Petition(s)”. In denying a pre-institution reply to address § 325(d), the Board in *Edwards Life Sciences* explained:

Petitioner was on notice prior to filing its Petition that, by statute, consideration may be given to whether the prior art or arguments presented in the Petition are the same, or substantially the same, as those previously raised during prosecution. Accordingly, Petitioner had the opportunity to address the issue in the Petition, and, given the limits on the length of a Petition, may not neglect to address an issue with the expectation that additional briefing will be permitted in reply.

Edwards Life Sci., Corp. v. Boston Scientific Scimed, Inc., IPR2017-00444, Paper 8 at 3 (P.T.A.B. May 22, 2017).

In this case, “Petitioner [also] had the opportunity to address the issue in the Petition” and made the strategic decision to dedicate only four sentences and irrelevant case law to the issue. Petitioner’s strategy of superficially treating a dispositive issue “with the expectation that additional briefing will be permitted in reply” should not be sanctioned, and any request for a pre-institution reply to further address § 325(d) should not be permitted. *See Helmerich & Payne Int’l Drilling Co., v. Nabors Drilling Techs. USA, Inc.*, IPR2021-00621, Paper 8 at 2-3 (P.T.A.B. July 15, 2021) (distinguishing bases for good cause in denying Petitioner’s request for pre-institution reply to address § 325(d) because Patent Owner’s arguments were

foreseeable, but granting Petitioner’s request to address new facts relating to § 314(a) and *Fintiv* that developed after the Petition was filed because they were not foreseeable).

III. CONCLUSION

All of Petitioner’s prior art was previously presented to the Office and Petitioner failed to meet its burden to show that the Examiner allegedly erred in a manner material to patentability of the Challenged Claims. The Board should thus “defer to previous Office evaluations of the evidence of record” and deny institution. *See Vital Connect*, IPR2023-00381, Paper 7 at 19-20 (citing *Advanced Bionics*).

Dated: January 18, 2024

/Peter J. McAndrews/
Peter J. McAndrews
Registration No. 38,547
McANDREWS, HELD & MALLOY
500 West Madison St., Suite 3400
Chicago, IL 60661
Telephone: (312) 775-8000

CERTIFICATE OF SERVICE

I hereby certify that the Patent Owner's Preliminary Response to Petition for *Inter Partes* Review Pursuant to 37 C.F.R. § 42.107 in connection with *Inter Partes* Review Case IPR2023-01409 was served on this 18th day of January, 2024 by electronic mail to the following:

Lead Counsel	Back-Up Counsel
John D. Vandenberg john.vandenberg@klarquist.com	Andrew M. Mason andrew.mason@klarquist.com Amy Haspel amy.haspel@klarquist.com
KLARQUIST SPARKMAN, LLP 121 SW Salmon Street, Suite 1600 Portland, Oregon, 97204 503-595-5300 (phone) 503-595-5301 (fax)	

Dated: January 18, 2024

/Peter J. McAndrews/
Peter J. McAndrews
Registration No. 38,547
McANDREWS, HELD & MALLOY
500 West Madison St., Suite 3400
Chicago, IL 60661
Telephone: (312) 775-8000

CUSTOMER NUMBER: 23446

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned attorney for the Patent Owner declares that this Patent Owner Preliminary Response has a total of 4,462 words, according to Microsoft Word® word count tool, excluding the parts of the Response exempted by 37 C.F.R. § 42.24(a)(1).

Dated: January 18, 2024

/Peter J. McAndrews/
Peter J. McAndrews
Registration No. 38,547
McANDREWS, HELD & MALLOY
500 West Madison St., Suite 3400
Chicago, IL 60661
Telephone: (312) 775-8000