

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

IPR2024-00860
Patent 11,510,625 B2

Before JAMES A. TARTAL, JON M. JURGOVAN, and
FREDERICK C. LANEY, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314; 37 C.F.R. § 42.4

I. INTRODUCTION

Abbott Diabetes Care Inc. (“Petitioner”)¹ filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–9, 13–19, and 22–30 of U.S. Patent No. 11,510,625 B2 (Ex. 1001, “the ’625 patent”). Paper 1 (“the ’860 Petition” or “Pet.”). DexCom, Inc. (“Patent Owner”)² filed a Preliminary Response. Paper 10 (“Prelim. Resp.”) Patent Owner also filed a statutory disclaimer under 35 U.S.C. § 253(a), dated August 21, 2024, disclaiming claims 22–27 of the ’625 patent. Ex. 2102. Accordingly, at this stage of the proceeding, only claims 1–9, 13–19, and 28–30 of the ’625 patent (the “Challenged Claims”) remain at issue. See 37 C.F.R. § 42.107(e) (providing that “[n]o *inter partes* review will be instituted based on disclaimed claims”).

Petitioner concurrently filed another petition in another proceeding requesting *inter partes* review of the same claims of the ’625 patent on different grounds. *Abbott Diabetes Care Inc. v. DexCom, Inc.*, IPR2024-00859, Paper 1 (PTAB May 9, 2024) (“the ’859 Petition”). Petitioner also filed an Explanation of Parallel Petitions Challenging U.S. Patent No. 11,510,625, and requested that we consider whether to institute *inter partes* review based on the ’859 Petition prior to considering the ’860 Petition. Paper 3 (“Exp.” or “Explanation”), 3–4. Patent Owner filed a Response to Petitioner’s Explanation of Parallel Petitions Challenging U.S. Patent No. 11,510,625. Paper 11 (“Exp. Resp.”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2023). In

¹ Petitioner further identifies Abbott Diabetes Care Sales Corp. and Abbott Laboratories as real-parties-in-interest. Pet. 2.

² Patent Owner identifies no additional real parties-in-interest. Paper 5, 1.

IPR2024-00859 (“the ’859 IPR”), we instituted *inter partes* review of claims 1–9, 13–19, and 28–30 of the ’625 patent. IPR2024-00859, Paper 12 (PTAB November 20, 2024). For the reasons provided below, and based on the circumstances present here, we find that Petitioner has failed to show that a second petition challenging the same claims of the ’625 patent at issue in the ’859 IPR is warranted and, accordingly, exercise discretion under 35 U.S.C. § 314(a) to deny institution of an *inter partes* review in this proceeding.

II. BACKGROUND

A. The ’625 Patent

The ’625 patent relates to “systems and methods for measuring an analyte in a host, and for applying a transcutaneous analyte measurement system to a host.” Ex. 1001, 2:11–13. The ’625 patent discloses that a transcutaneous analyte measurement system, such as an on-skin sensor assembly, may be used to continuously monitor glucose levels in a patient. *Id.* at 1:55–57. “The sensor system may have a wireless transmitter which transmits measurement data to a receiver which can process and display information based on the measurements.” *Id.* at 1:57–60. According to the ’625 patent, the application process for the transcutaneous analyte measurement system “should result in the sensor assembly being attached to the person in a state where it is capable of sensing glucose level information, communicating the sensed data to the transmitter, and transmitting the glucose level information to the receiver.” *Id.* at 1:62–67.

Figure 72 of the ’625 patent, reproduced below, illustrates an exploded perspective view of an applicator for an on-skin sensor assembly of an analyte sensor system. Ex. 1001, 17:32–36.

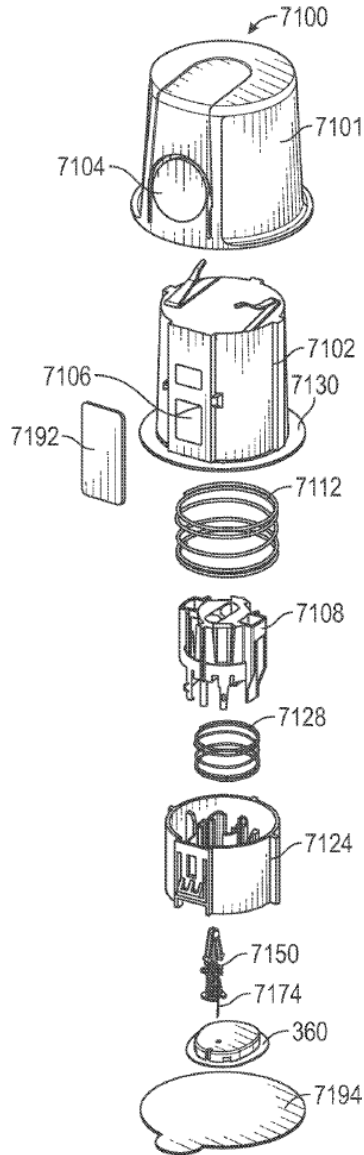


FIG. 72

As illustrated in Figure 72, applicator 7100 includes outer applicator housing 7101, inner housing 7102, needle carrier assembly 7108, holder 7124, an insertion assembly, and a retraction assembly. Ex. 1001, 58:52–59:66. The outer applicator housing 7101 comprises activation element 7104 and “may be configured to translate in a distal direction by a force applied by a host to applicator 7100, specifically to inner housing 7102, thereby aligning activation element 7104 in a position that allows applicator 7100 to fire.” *Id.* at 58:55–59.

Inner housing 7102 is configured to house at least one or more mechanisms to apply on-skin sensor assembly 360 to the skin of a host. Ex. 1001, 58:62–65. Inner housing 7102 may include distal surface 7130 that defines a bottom surface 7100 of the applicator and may have aperture 7106 that is covered with first barrier layer 7192 which is pierced or deformed by at least a portion of activation element 7104 upon activation of applicator 7100. *Id.* at 58:65–67, 59:7–14. Inner housing 7102 may also include second barrier layer 7194 disposed over the bottom opening which may be removed by the host prior to use of applicator 7100. *Id.* at 60:27–28, 31–33. “In embodiments comprising one or both of first and second barrier layers 7192, 7194, such layers may provide a sterile environment between applicator 7100 and the outside environment and/or may allow ingress and egress of gas such as during sterilization.” *Id.* at 60:33–37.

Needle carrier assembly 7108 includes “needle hub 7150 configured to couple an insertion element 7174 to needle carrier assembly 7108.” Ex. 1001, 59:18–21. Insertion element 7174 inserts the sensor of on-skin sensor assembly 360 into the host’s skin and may comprise any suitable type of needle or structure. *Id.* at 59:23–30. Holder 7124 is releasably coupled to needle carrier assembly 7108 and configured to guide needle carrier assembly 7108 and on-skin sensor assembly 360 “at least during translation from a proximal position to a distal insertion position.” *Id.* at 59:35–40. On-skin sensor assembly 360 “may be stripped or released from holder 7124 and/or needle carrier assembly 7108” once the on-skin sensor assembly is disposed on the host’s skin. *Id.* at 59:40–44.

The insertion assembly may include first spring 7112 with “a first end in contact with or coupled to inner applicator housing 7102 and a second end in contact with or coupled to holder 7124.” Ex. 1001, 59:49–54. First

spring 7112 is configured to translate holder 7124, needle carrier assembly 7108, needle hub 7150, insertion element 7174, and on-skin sensor assembly 360 in the distal direction to the distal insertion position upon activation of the insertion assembly. *Id.* at 59:54–58. The retraction assembly may include second spring 7128 with “a first end contacting or coupled to holder 7124 and a second end in contact with or coupled to at least one spring retention element . . . , at least until retraction.” *Id.* at 60:2–8. Second spring 7128 is configured to translate needle carrier assembly 7108, needle hub 7150, and insertion element 7174 from the distal insertion position to the proximal retracted position in response to on-skin sensor assembly 360 contacting the host’s skin “and/or reaching a limit of travel with a force exceeding a predetermined threshold sufficient to cause first end of second spring 7128 to overcome the at least one spring retention element.” *Id.* at 60:8–17.

Figure 77 of the '625 patent, reproduced below, illustrates a perspective partial cutaway view of the needle carrier assembly, hub, and on-skin sensor assembly of the applicator shown in Figure 72.

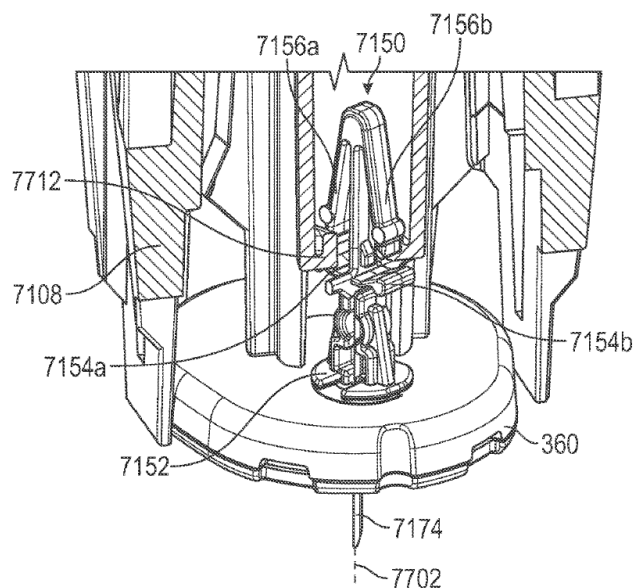


FIG. 77

Figure 77 includes needle carrier assembly 7108, needle hub 7150, and on-skin sensor assembly 360. Ex. 1001, 67:63–66. Needle hub 7150 includes “a plurality of upper arms 7156a, 7156b, a plurality of lower arms 7154a, 7154b, and a base 7152” and is configured to “couple insertion element 7174 to needle carrier assembly 7108 and to substantially maintain a desired orientation of insertion element 7174 during insertion of the sensor of on-skin sensor assembly 360 into the skin of the host.” *Id.* at 68:7–14. Upper arms 7156a, 7156b and lower arms 7154a, 7154b “may be flexible such that, when needle hub 7150 is coupled to needle carrier assembly 7108, upper arms 7156a, 7156b and lower arms 7154a, 7154b secure needle hub 7150 in a desired orientation with respect to needle carrier assembly 7108” by flexing radially inward when disposed through carrier aperture 7712 in needle carrier assembly 7108, and expanding after clearing the surface of carrier aperture 7712. *Id.* at 68:16–33.

Base 7152 of needle hub 7150 includes an anti-rotation feature which may comprise a key having a shape complementary to at least a portion of a sensor assembly aperture of on-skin sensor assembly 360 and “may be configured to substantially prevent needle hub 7150 from rotating about an axis 7702 parallel to insertion element 7174 with respect to on-skin sensor assembly 360, e.g., to prevent rotation of base 7152 within sensor assembly aperture 396.” Ex. 1001, 68:41–48. Base 7152 may further comprise “a substantially flat surface configured to mate with a top surface of on-skin sensor assembly 360 and maintain insertion element 7174 in a substantially perpendicular orientation to the top surface of on-skin sensor assembly 360.” *Id.* at 68:57–64.

B. Illustrative Claim

Of the Challenged Claims, claims 1, 13, and 28 are independent. Claims 2–9 depend from claim 1, claims 14–19 depend from claim 13, and claims 29 and 30 depend from claim 28. Claim 1 is illustrative of the claimed subject matter and is reproduced below:

1. An applicator for applying an on-skin sensor assembly to a skin of a host, the applicator comprising:
 - an applicator housing having an internal volume;
 - a needle hub coupled to an insertion element configured to pierce a skin of a host, the needle hub comprising:
 - a base, and
 - an anti-rotation feature extending from the base,
 - the anti-rotation feature comprising a key, the key having a first shape; and
 - an on-skin sensor assembly comprising:
 - a sensor, the sensor configured to measure a glucose concentration of a host, and
 - an aperture extending from a top surface of the on-skin sensor assembly,
 - the aperture having a second shape, the second shape complementary to the first shape of the key; and
- wherein the key of the anti-rotation feature is configured to be at least partially disposed in the aperture of the on-skin sensor assembly; and
- wherein the anti-rotation feature is configured to prevent rotation of the needle hub within the aperture.

Ex. 1001, 98:32–52.

C. Asserted Grounds of Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. § ³	Reference(s)/Basis
1–9, 13–19, 28–30	103	Rao ⁴
4, 5, 14, 15, 30	103	Rao, Lundquist ⁵

Pet. 4. Petitioner’s contentions are supported by the Declaration of Cameron Riviere, Ph.D., dated May 8, 2024. Ex. 1004.

D. Related Proceedings

Petitioner and Patent Owner identify *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, No. 1:23-cv-00239 (D. Del) and *Abbott Diabetes, Inc. v. DexCom, Inc.*, IPR2024-00859 (PTAB) as related proceedings. Pet. 2; Exp. 1; Paper 5, 1. Patent Owner also states that U.S. Application No. 17/960,550 and U.S. Application No. 17/960,425 “claim priority to U.S. Patent Application No. 17/592,170, from which U.S. Patent No. 11,510,625 issued.” Paper 5, 1.

III. ANALYSIS

Because Petitioner concurrently filed multiple petitions challenging the same claims of the same patent, we first consider whether we should exercise discretion to deny the ’860 Petition in light of our determination to institute *inter partes* review in the ’859 IPR. *See* 35 U.S.C. § 314(a); *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) (explaining that section “314(a) invests the Director with discretion on the question *whether* to

³ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. We apply the AIA version of § 103 here, because the ’625 patent does not reflect a priority date earlier than the effective date of the AIA. *See* Ex. 1001, codes (22), (60), (63), (65).

⁴ U.S. Patent App. Pub. No. US 2018/0235520 A1, published Aug. 23, 2018 (Ex. 1012, “Rao”).

⁵ U.S. Patent App. Pub. No. US 2014/0188053 A1, published Jul. 3, 2014 (Ex. 1011, “Lundquist”).

institute review”); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.”). More specifically, the Patent Trial and Appeal Board Consolidated Trial Practice Guide (84 Fed. Reg. 64,280 (Nov. 21, 2019))⁶ (“CTPG”) states that generally “one petition should be sufficient to challenge the claims of a patent in most situations” and that “multiple petitions by a petitioner are not necessary in the vast majority of cases.” CTPG 59.

According to the CTPG, “[t]wo or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by the patent owner) may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns.” *Id.* (citing 35 U.S.C. § 316(b)). The CTPG also sets forth the following guidance:

To aid the Board in determining whether more than one petition is necessary, if a petitioner files two or more petitions challenging the same patent, then the petitioner should, in its petitions or in a separate paper filed with the petitions, identify: (1) a ranking of the petitions in the order in which it wishes the Board to consider the merits, if the Board uses its discretion to institute any of the petitions, and (2) a succinct explanation of the differences between the petitions, why the issues addressed by the differences are material, and why the Board should exercise its discretion to institute additional petitions if it identifies one petition that satisfies petitioner’s burden under 35 U.S.C. § 314(a).

Id. at 59–60 (footnote omitted). In the Explanation, Petitioner argues that “[t]wo petitions were required for two reasons.” Exp. 1. For the following reasons we agree with Patent Owner that Petitioner has not shown that a

⁶ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

parallel petition challenging claims 1–9, 13–19, and 28–30 of the ’625 patent is warranted. *See* Exp. Resp. 1–4.

First, Petitioner contends “[e]ach petition involves different prior art references, and therefore presents materially different grounds for challenging the patent, even though both petitions challenge all claims of the ’625 patent that Patent Owner has asserted against Petitioner in the district court litigation.” *Id.* at 2. To the contrary, both petitions rely, in part, on the same art, Lundquist, indicating that there is a degree of overlap between the two petitions. Moreover, the mere fact that Petitioner is relying on Rao only in the ’860 Petition fails to show any rational reason a second petition is necessary. Remarkably, rather than suggest Rao is materially different or superior over the art asserted in the ’859 Petition for any reason relevant to our patentability analysis, Petitioner instead concedes that Rao is more problematic for Petitioner because Rao is only prior art if Petitioner can show that the ’625 patent is not entitled to its earliest priority date. *See* Exp. 1–3 (explaining that Patent Owner “may challenge whether Rao is prior art because of a dispute about the effective filing date of the ’625 patent”).

We agree with Patent Owner that, outside of a potential priority dispute, Petitioner makes no comparison between the references relied on in the two parallel petitions in regard to the patentability issues raised and, specifically, does not “attempt to explain why the disclosures of Rao are materially different and not cumulative of the references in [the ’859 Petition].” Exp. Resp. 2 (citing *See Square, Inc. v. 4361423 Canada Inc.*, IPR2019-01626, Paper 14 at 9 (P.T.A.B. Mar. 30, 2020) (explaining that a petitioner is not entitled to file two petitions against the same claims of the same patent by merely implicating a priority issue). In short, Petitioner’s assertion that Rao may be more problematic for Petitioner to rely upon as

prior art is not a persuasive reason why Petitioner requires a second petition challenging the same claims of the '625 patent. *See* Exp. 1–3. Absent from Petitioner's argument is any explanation for why the Board should exercise its discretion to institute the '860 Petition as an additional petition having decided first that the '859 Petition satisfied Petitioner's burden for purposes of instituting review of the '625 patent on numerous grounds raised in the '859 IPR. *See* CTYG, 59–60.

Second, Petitioner argues that “the length and number of challenged claims justify multiple petitions” because “Patent Owner asserts infringement of 25 claims, including four independent claims, in the district court litigation” and “[t]he asserted claims are lengthy, including more than 1,000 words in total.” Exp. 3. According to Petitioner, it “requires additional words to challenge the asserted claims, despite its best efforts to narrow the unpatentability issues presented to the Board.” Exp. 3. Petitioner's assertions in this regard are not credible or persuasive.

In the '859 Petition, rather than narrow the unpatentability issues, Petitioner asserts multiple grounds against every claim challenged, including allegations based on multiple embodiments of the same reference, as well as grounds based on three different primary references. *See* '859 Petition. Petitioner provides no explanation for why the grounds raised in the '859 Petition are not duplicative, much less why the additional grounds raised in the '860 Petition are not duplicative of the grounds raised in the '859 Petition. We further agree with Patent Owner that the number of claims challenged is unremarkable, and that Petitioner neglects the fact that “there is substantial overlap between the language of the '625 Patent's independent and dependent claims, as reflected by the ['859] Petition's reliance throughout on its earlier claim analysis for subsequent claims with

similar language.” Exp. Resp. 3–4 (citing ’859 Petition 57–59 (citing to prior claim 1 analysis as satisfying 11 distinct limitations of claim 28 without additional analysis). We agree with Patent Owner that this overlap “has lessened Petitioner’s burden in presenting its challenge within the mandated word limits.” *Id.* at 4. Based on these circumstances, we find that the reasons provided by Petitioner do not show that a parallel petition is warranted.

IV. CONCLUSION

We have reviewed the ’860 Petition and the ’859 Petition, along with Petitioner’s Explanation in support of multiple petitions, and determine that, on the record present here, Petitioner has not set forth adequate reasoning that supports the institution of multiple *inter partes* reviews based on two petitions both directed to claims 1–9, 13–19, and 28–30 of the ’625 patent. *See generally* Exp. Accordingly, in light of our determination to institute *inter partes* review on all grounds presented in the ’859 Petition, we exercise discretion under 35 U.S.C. § 314(a) to deny institution of the ’860 Petition in this proceeding.

V. ORDER

Upon consideration of the record before us, it is:

ORDERED that the ’860 Petition is denied and no trial is instituted in this proceeding.

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