Trials@uspto.gov
571-272-7822

Paper 13
Date: April 16, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,

Petitioner,

v.

ABBOTT DIABETES CARE INC.,

Patent Owner.

IPR2023-01396
Patent 11,266,335 B2

Before JOHN G. NEW, RYAN H. FLAX, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Petitioner Dexcom, Inc. ("Petitioner") has filed a Petition (Paper 3, the "Petition" or "Pet.") seeking *inter partes* review of claims 1–4, 8, 9, and 11–27 of U.S. Patent 11,266,335 B2 (Ex. 1001, the "'335 patent"). Patent Owner Abbott Diabetes Care Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 7 (the "Preliminary Response" or "Prelim. Resp.").

Because the present Petition is one of two challenging the same claims of the '335 patent[1], Petitioner filed an Explanation of the Material Differences between the Petitions. Paper 2 (the "Explanation" or "Expl."); *see* Patent Trial and Appeal Board *Consolidated Trial Practice Guide* (November 2019) ("CTPG") at 59–60.[2] Patent Owner filed a Response to Petitioner's Explanation concurrently with its Preliminary Response. Paper 8 (the "Explanation Response" or "Expl. Resp."). The arguments in the Explanation and Explanation Response pertain to a prior art reference cited in the parallel Petition in IPR2023-01397, and we address the arguments raised in these papers in our Decision Denying Institution entered in that case. *See* IPR2023-01397, Paper 13.

Under 35 U.S.C. § 314, the Board "may not authorize an *inter partes* review to be instituted unless … the information presented in the petition … and any response … shows that there is a reasonable likelihood that the

[1] The other Petition seeking *inter partes* review of challenged claims 1–4, 8, 9, and 11–27 of the '335 patent is in *Dexcom, Inc. v. Abbott Diabetes Care Inc.*, IPR2023-01397 (filed October 6, 2023).

[2] *Available at*: https://www.uspto.gov/TrialPracticeGuideConsolidated.

petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petition, Patent Owner's Preliminary Response, the Explanation, the Explanation Response, and the evidence of record as presently developed, we determine that the evidence presented fails to demonstrate a reasonable likelihood that Petitioner would ultimately prevail at trial in establishing the unpatentability of the challenged claims of the '335 patent. We consequently deny institution of *inter partes* review.

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies Dexcom, Inc. as its sole real party-in-interest. Pet. xi. Patent Owner identifies Abbott Diabetes Care Inc. as its real party-in-interest. Paper 6 at 1.

B. Related Matters

Patent Owner and Petitioner each identify as a related matter an infringement action filed by Patent Owner against Petitioner, *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, No. 1:23-cv-00239 (D. Del.), filed March 3, 2023, asserting infringement of the '335 patent. Pet. xi; Paper 6, 1.

The parties also identify as a related proceeding a parallel *inter partes* review challenging claims 1–4, 8, 9, and 11–27 of the '335 patent, *Dexcom, Inc. v. Abbott Diabetes Care Inc.*, IPR2023-01397, filed October 6, 2023. Pet. xi; Paper 6, 1; *see supra* fn. 1.

The parties also identify, as a related matter, a third *inter partes* review Petition challenging claims 5–7 of the '335 patent, *Dexcom, Inc. v. Abbott Diabetes Care Inc.*, IPR2024-00520, filed January 31, 2024. Paper 10, 2; 11, 1.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–4, 8, 9, and 11–27 of the '335 patent are unpatentable, based upon the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–4, 8, 9, 11–27	103(a)[3]	Stafford[4], Raymond[5]
2	1–4, 8, 9, 11–27	103(a)	Stafford, Raymond, Turner[6]
3	16	103(a)	Stafford, Raymond, Say[7]
4	16	103(a)	Stafford, Raymond, Turner, Say

[3] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the application from which the '335 patent issued has an effective filing date prior to that date, the pre-AIA version of § 103 applies.

[4] Stafford (US2008/0097246 A1, April 24, 2008) ("Stafford"), Ex. 1009.

[5] Raymond et al. (US 2009/0124979 A1, May 14, 2009) ("Raymond"), Ex. 1010.

[6] Turner et al. (US 2007/0135774 A1, July 14, 2007) ("Turner"), Ex. 1011.

[7] Say et al. (US 6,175,752 B1, January 16, 2001) ("Say"), Ex. 1012.

5	16	103(a)	Stafford, Raymond, Bickoff[8]
6	16	103(a)	Stafford, Raymond, Turner, Bickoff
7	17–18	103(a)	Stafford, Raymond, Shah[9]
8	17–18	103(a)	Stafford, Raymond, Turner, Shah

Petitioner also relies upon the Declaration of Gary D. Fletcher, Ph.D. (Ex. 1003, the "Fletcher Declaration").

D. The '335 Patent

The '335 patent is directed to an apparatus for inserting a medical device in the skin of a subject, as well as methods of inserting such medical devices. Ex. 1001, Abstr. Specifically, the '335 patent discloses, in certain embodiments, an apparatus that includes (1) a sheath defining a distal surface for placement on the skin of the subject; (2) a device support movable between a proximal and distal position, and adapted to support the medical device; (3) a sharp (i.e., a needle) support movable between a proximal and a distal position and adapted to support the sharp for inserting the medical device into the skin of the subject; (4) a device support comprising a first engagement member for releasably coupling the sharp

[8] Bickoff (US 2009/0240121 A1, September 24, 2009) ("Bickoff"), Ex. 1013.

[9] Shah et al. (US 2007/0073129 A1, March 29, 2007) ("Shah"), Ex. 1014.

support to the device support and a second engagement member for engaging the medical device; (5) a handle movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from a proximal to a distal position to insert the sharp into the skin of the subject; and (6) a driver for advancing the sharp support towards the proximal position when the sharp support reaches the distal position. Ex. 1001, cols. 2–3, ll. 62–12.

Figures 61 and 63 of the '335 patent illustrate an embodiment of the claimed medical insertion device, with medical device 122 and sharp 2404 in the proximal (Figure 61) and distal (Figure 63) positions:

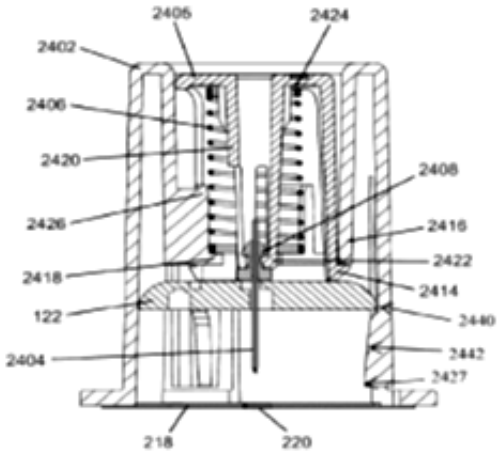


FIG. 61

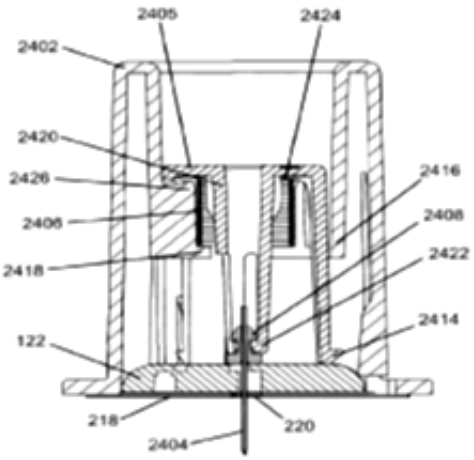


FIG. 63

Figures 61 and 63 of the '335 patent depict a cross-sectional view of the claimed medical insertion device with sharp 2404 and the base of the medical device 122 in the proximal (i.e., retracted) position (Figure 61) and in the distal (i.e., extended) position (Figure 63)

The '335 patent teaches that, when the sharp is in the proximal position, both prior to, and after, insertion of the medical device into the

skin, the needle is retracted inside the device to prevent any accidental touching of the needle by the user. Ex. 1001, col. 40, ll. 50–51, Fig. 106.

Of particular relevance to our inquiry in this Decision is the '335 patent's disclosure relating to independent claim 1's recited limitation:

> [A]n on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter; the glucose sensor.

Ex. 1001, col. 48, ll. 58–65.

Figure 125 of the '335 patent depicts on-body electronics unit housing 322, with one of the plurality of peripheral recesses 3766 visible in this perspective view:

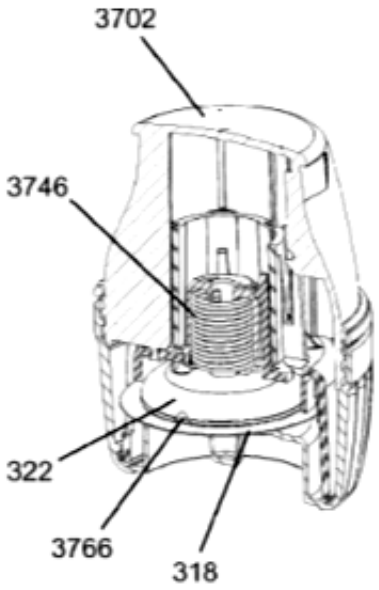


FIG. 125

Figure 125 of the '335 patent is a perspective, cutaway view of an embodiment of the claimed medical insertion device, depicting the on-body electronics unit housing 322 with one of the plurality of peripheral recesses 3766 visible in this view

Figure 124 of the '335 patent is a similar view to Figure 125, depicting the medical device carrier 3730 extending over, and detachably engaging, the recesses of on-body electronics unit housing 322 (not visible in this view). Figure 124 is reproduced below:

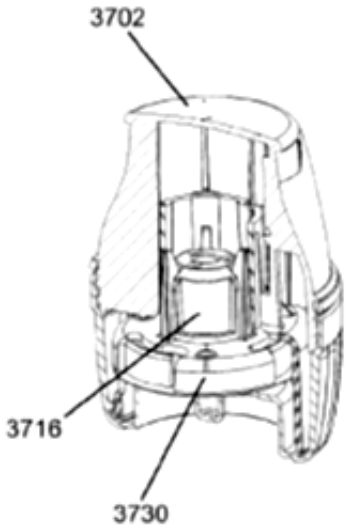


FIG. 124

Figure 124 of the '335 patent is a perspective, cutaway view of an embodiment of the claimed medical insertion device, depicting the medical device carrier 3730 engaging the electronics unit housing 322

An enlarged view of medical device carrier 3730 is depicted in Figure 122 of the '335 patent, which is reproduced below:

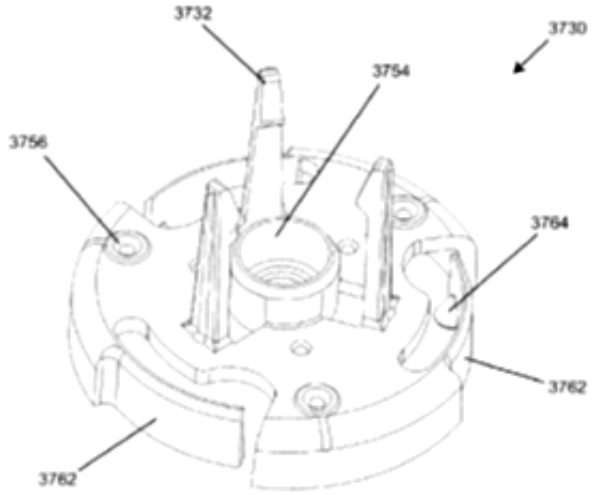


FIG. 122

Figure 122 of the '335 patent depicts a perspective view of the medical device carrier 3730

As shown in Figure 122, the medical device carrier has a plurality of housing gripping arms 3762 (three are depicted in Figure 122) which detachably hold the on-body electronics unit housing 322 in place. Ex. 1001, col. 44, ll. 6–12. The housing gripping arms 3762 are each provided with engagement boss 3764, configured to engage with corresponding recesses 3766 provided on the side walls of the on-body electronic unit housing 322. *Id.*

E. Representative Claim

Challenged claim 1 is the only independent claim of the '335 patent, and is representative of the remaining challenged claims. Challenged claim 1 recites:

1. A glucose monitoring assembly, the assembly comprising:
(1) an inserter comprising

a sharp configured to insert a portion of a glucose sensor into a subject; and

(2) an on body electronics unit, comprising:

an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter;

the glucose sensor; and

on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

Ex. 1001, cols. 48–49, ll. 53–12.

F. Priority History of the '335 Patent

The '335 patent issued from US Application Ser. No. 17/019,110, filed on September 11, 2020 (Ex. 1001, codes (21), (22)), and claims priority through a series of continuation applications to an application that was filed on March 24, 2011, and also claims the priority benefit of US Provisional

Application Ser. No. 61/317,243, which was filed on Mar. 24, 2010. *Id.* at code (60). The '335 patent issued on March 8, 2022. Ex. 1001, code (45).

III. CLAIM CONSTRUCTION AND LEVEL OF ORDINARY SKILL IN THE ART

A. Claim Construction

The Board applies the same claim construction standard here that would be used to construe claim language in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 100(b) (2020). Under that standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence may also be consulted, but is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Neither Petitioner nor Patent Owner offers any express construction of any of the claim terms of the '335 patent, but both argue, rather, that the plain and ordinary meaning of all claim terms should be applied. Pet. 12, Prelim. Resp. 32. We consequently determine that no express construction of any claim term is necessary for purposes of rendering this Decision.

Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co., 868 F.3d 1013, 1017 (Fed. Cir. 2017).

B. A Person of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art at the time of invention would have had a bachelor's degree in bioengineering, mechanical engineering, electrical engineering, or a related subject, and one or more years of experience researching, developing, and/or designing insertable medical devices, including, e.g., systems for implanting wearable medical devices such as cannulas, infusion sets, and analyte sensors, or equivalent experience. Pet. 8. Petitioner also proposes that less work experience could be compensated by a higher level of education, such as a master's degree, and *vice versa*. *Id.* (citing Ex. 1003 ¶ 24). Patent Owner does not dispute Petitioner's definition of a person of ordinary skill in the art. Prelim. Resp. 32.

Petitioner's proposed definition of the level of ordinary skill in the art appears to be consistent with the level of skill presented in the cited prior art. *See, e.g.*, Exs. 1003, Exs. 1009–1011, 1018, 1057; *see Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself may reflect an appropriate level of skill in the art). For the purposes of this Decision, then, we adopt Petitioner's proposed definition as the definition of a person of ordinary skill in the art.

IV. ANALYSIS

A. Principles of Law

1. Burden of Proof

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016 (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity … the evidence that supports the grounds for the challenge to each claim")). Therefore, in an *inter partes* review, the burden of proof is on the Petitioner to show that the challenged claims are unpatentable; that burden never shifts to the patentee. *See* 35 U.S.C. § 316(e); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016) (citing *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015)). At the institution stage, Petitioner must show a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314.

2. Obviousness

To ultimately prevail in its challenge to Patent Owner's patent claims, Petitioner must demonstrate by a preponderance of the evidence[10] that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). A patent

[10] The burden of showing something by a preponderance of the evidence requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before the trier of fact may find in favor of the party who carries the burden. *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 622 (1993).

claim is unpatentable under pre-AIA 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103(a) (2006); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of obviousness or nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In determining obviousness when all elements of a claim are found in various pieces of prior art, "the factfinder must further consider the factual questions of whether a person of ordinary skill in the art would be motivated to combine those references, and whether in making that combination, a person of ordinary skill would have had a reasonable expectation of success." *Dome Patent L.P. v. Lee*, 799 F.3d 1372, 1380 (Fed. Cir. 2015); *see also WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999) ("When an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references."). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988); *see also In re Magnum Oil Tools*, 829 F.3d at 1381 (finding a party that petitions the Board for a determination of unpatentability based on obviousness must

show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so").

An obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *see also In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). In *KSR*, the Supreme Court also stated that an invention may be found obvious if trying a course of conduct would have been obvious to a person of ordinary skill in the art:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

550 U.S. at 421. "*KSR* affirmed the logical inverse of this statement by stating that § 103 bars patentability unless 'the improvement is more than the predictable use of prior art elements according to their established functions.'" *In re Kubin*, 561 F.3d 1351, 1359–60 (Fed. Cir. 2009) (citing *KSR*, 550 U.S. at 417).

We analyze the asserted grounds of unpatentability in accordance with the above-stated principles.

B. Ground 1: Obviousness under 35 U.S.C. § 103(a) of Claims 1–4, 8, 9, and 11–27 over Stafford (Ex. 1009) and Raymond (Ex 1010)

1. Overview of the Prior Art

a. Stafford

Stafford is US Appl. 2008/0097246 A1, published on April 24, 2008, and is prior art to the '335 patent. Ex. 1009, codes (10), (43).

Stafford is directed to "methods and apparatus for providing an integrated analyte sensor and data processing unit assembly." Ex. 1009, Abstr. Specifically, Stafford teaches an integrated assembly, including: (1) a housing; (2) a data processing unit disposed within the housing; (3) an introducer removably coupled to the housing; (4) at least a portion of the introducer disposed within the housing; and (5) an analyte sensor coupled to the housing. *Id.* ¶ 6. Stafford further teaches that a first portion of the analyte sensor is configured for subcutaneous placement, and, when placed, is in fluid contact with an interstitial fluid of the subject. *Id.* Stafford teaches that a second portion of the analyte sensor is disposed within the housing and is in electrical communication with the data processing unit. *Id.*

Figure 4A of Stafford depicts an exemplary embodiment of such an apparatus and is reproduced below:

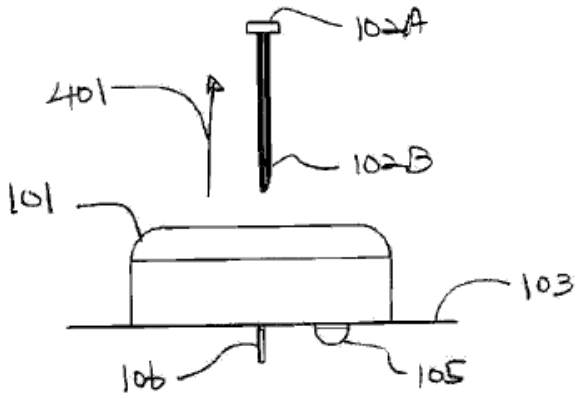


FIGURE 4A

Figure 4A is a schematic diagram of an integrated analyte sensor delivery and data processing unit with introducer 102 removed and the first portion of analyte sensor 106 implanted.

Stafford teaches that the first portion of its introducer 102B has a sharp tip that pierces the subject's skin 103 to deliver the sensor subcutaneously. Ex. 1009 ¶¶ 21, 24, Figs. 4A, 5B–5C. Specifically, Stafford teaches that the inserter is configured to pierce through the skin of the patient and concurrently guide the sensor through the patient's skin so as to place at least a portion of the sensor in fluid contact with the target biological fluid of the subject. *Id.* ¶ 2. Stafford explains that once the sensor 106 is accurately positioned, the inserter 102 is removed and discarded, and that doing so "requires a level of care" to avoid injury from the introducer's sharp tip. *Id.* ¶ 3. Stafford cautions that "particular precautions" should be taken to avoid contact with the tip (e.g., the first portion 102B), after contact with the subject's biological fluids. *Id.*

Stafford also teaches that its data processing unit 101 includes electronics, e.g., a processor, a power supply, and an RF transceiver for wirelessly transmitting sensor data. Ex. 1009 ¶¶ 40, 52, Fig. 7.

b. Raymond

Raymond is US Appl. US 2009/0124979 A1, published on May 14, 2009, and is prior art to the '335 patent. Ex. 1010, codes (10), (43).

Raymond is directed to "[a]n insertion device for inserting an infusion device at least partially into skin for subcutaneous infusion." Ex. 1010, Abstr. Specifically, Raymond teaches an inserter for placing an infusion device comprising: (1) a sleeve; (2) a carriage; (3) at least at first biasing member; (4) a hub; (5) a needle; (6) at least a second biasing member; and (7) an actuator. *Id.* ¶ 15.

Figures 29 and 30, reproduced below, depict a relevant embodiment of Raymond:

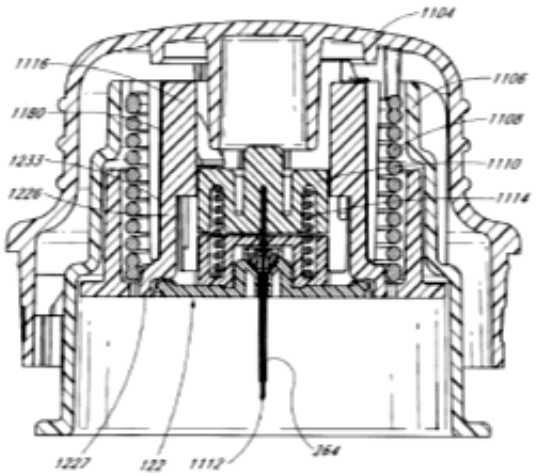


FIG. 29

Figure 29 of Raymond depicts a cross-sectional view of an insertion device with sharp 1112, cannula 264 and base 122 in the proximal position

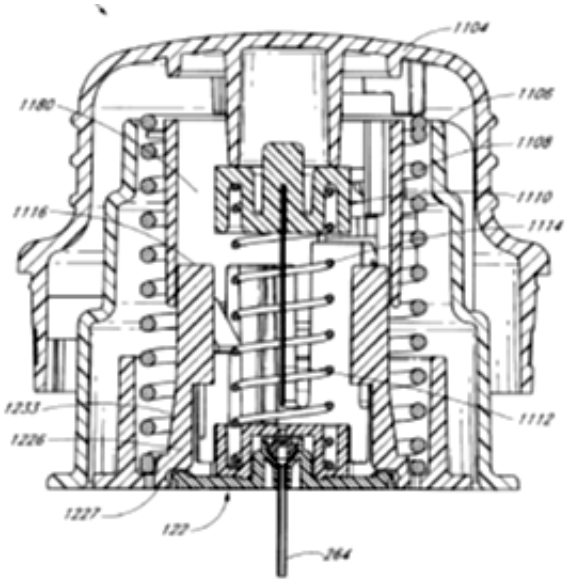


FIG. 30

Figure 30 of Raymond depicts a cross-sectional view of an insertion device with cannula 264 and base 122 in the distal position

As pictured above, Figure 29 of Raymond depicts the insertion device with needle 1112 and canula 264, and the base of the infusion device 122 in a proximal (retracted) position prior to injection and insertion through the skin of the subject (at the base of the device). Raymond's Figure 30 depicts the canula 264 and the base of infusion device 122 in a distal (extended) position subsequent to injection and insertion through the skin. Raymond further teaches that base 122 is held in position in the proximal position by base-retaining arms 1226.

Raymond teaches several advantages of its insertion device, including positioning the needle within the insertion device before insertion and retracting the needle within the insertion device after insertion to prevent accidental injury to the user. Ex. 1010 ¶¶ 8, 104, 109, 127.

2. Petitioner's argument

Petitioner argues that the combination of Stafford and Raymond combines Stafford's teachings related to a glucose sensor, introducer (i.e., the claimed "sharp"), integrated assembly ("on-body electronics unit"), and housing ("on body electronics unit housing") and Raymond's teachings related to an insertion device ("inserter") with base-retaining arms ("gripping arms"). Pet. 19 (citing Ex. 1003 ¶ 48). Petitioner argues that the combination of Stafford and Raymond includes the following elements cooperating as listed below:

> an insertion device as taught by Raymond, adjusted to accommodate and engage a housing as taught by Stafford, and to use a needle/introducer to insert a portion of a glucose sensor similar to that taught by Stafford beneath the skin of a subject; and
>
> an integrated assembly as taught by Stafford, including:
>
> > the housing adjusted to include spaced-apart recesses disposed on a periphery of the housing, with the recesses detachably engageable with the insertion device as taught by Raymond;
> >
> > a glucose sensor; and
> >
> > electronics coupled to the glucose sensor, in which the electronics include a memory, processor, power supply, and RF transceiver for wirelessly communicating glucose level data;
>
> wherein the insertion device is configured to advance the integrated assembly and needle/introducer from a proximal position entirely within the insertion device to a distal position, and
>
> wherein the insertion device is further configured to retract the needle/introducer from the distal position to a retracted position entirely within the insertion device.

Id. at 20–21.

a. Claim 1

i. [1.1] A glucose monitoring assembly, the assembly comprising:

Petitioner argues that Stafford expressly teaches a glucose sensor. Pet. 26 (citing Ex. 1003 ¶ 61; Ex. 1009 ¶ 51).

ii. [1.2] an inserter comprising:

Petitioner argues that both Stafford and Raymond expressly teach an inserter. Pet. 27.

iii. [1.3] a sharp configured to insert a portion of a glucose sensor into a subject; and

Petitioner contends that Stafford teaches an introducer ("sharp"), including a lower portion for inserting Stafford's sensor. Pet. 27 (citing Ex. 1003 ¶ 65; Ex. 1009 ¶ 28, Fig. 5C). Petitioner argues that Raymond's insertion device ("inserter") also includes a needle (i.e., a "sharp") for inserting a cannula. *Id.* (citing Ex. 1003 ¶ 66; Ex. 1010 ¶ 109, Figs. 29–30).

According to Petitioner, a person of ordinary skill in the art would have employed a sharp such as that disclosed in Stafford so as to be compatible with the glucose sensor as taught by Stafford, and would have had a reasonable expectation of success of doing so. Pet. 27 (citing Ex. 1003 ¶ 67).

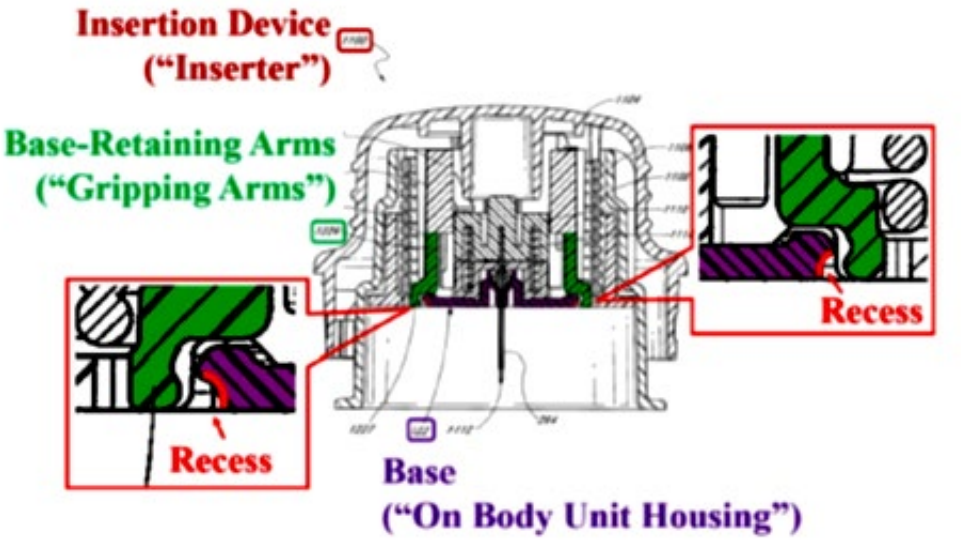
iv. [1.4] an on body electronics unit, comprising:

Petitioner argues that with respect to limitation [1.5] below, the combination of Stafford and Raymond includes an "on body electronics unit." Pet. 28 (citing Ex. 1003 ¶ 69).

v. [1.5] an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter;

Petitioner argues that the combination of Stafford and Raymond teaches an assembly ("on body electronics unit") that comprises a housing ("on-body electronics unit housing") containing electronics and configured to be adhered to a subject's body. Pet. 28 (citing Ex. 1003 ¶¶ 70–71; Ex. 1009 ¶¶ 19, 40, 52, Fig. 7).

Petitioner contends that Raymond teaches an insertion device with "base-retaining arms" that "engage" the on-body electronics unit. Pet. 28 (citing Ex. 1003 ¶ 72; Ex. 1010 ¶ 123). Specifically, Petitioner asserts that Raymond teaches arms with inward protrusions, called "base-retaining feet," that "engage the base" of the on-body unit "and secure it" to the insertion device. *Id.* (citing Ex. 1003 ¶ 72; Ex. 1010 ¶ 123). Petitioner points to its colored and annotated version of Raymond's Figure 29 (reproduced below) as illustrating how each of these feet/protrusions on the arms (shown in green) detachably engages recesses (outlined in red) disposed on opposite sides of the base of the "on body unit housing" (shown in purple). *Id.* at 28–29 (citing Ex. 1003 ¶ 72; Ex. 1010 ¶¶ 126, 127–128, Figs. 29–30).



Petitioner's colored and annotated version of Raymond's Figure 29

Petitioner acknowledges that the text of Raymond's Specification does not expressly describe these recesses, but argues, based on the figures of Raymond, that a skilled artisan would have at least found it obvious to implement an on-body unit with recesses to engage the feet/protrusions of the retaining arms. Pet. 29 (citing Ex. 1003 ¶ 73; Ex. 1010, Figs. 29–30; also citing, e.g., *In re Aslanian*, 590 F.2d 911, 914 (C.C.P.A. 1979)).

According to Petitioner, a person of ordinary skill in the art would have known that feet/protrusions, like those taught by Raymond, were regularly designed to engage corresponding recesses or notches on associated components, in order to retain the components in relative position to one another. Pet. 30 (citing Ex. 1003 ¶ 74; Ex. 1018 ¶ 11; Ex. 1040, col. 2, ll. 45–57; Ex. 1042 ¶ 10; Ex. 1057 ¶ 15). Petitioner notes that Raymond elsewhere employs a similar concept, describing a bounded recess on one component that engages a foot/protrusion on another component "to prevent unintentional rotation." *Id.* (citing Ex. 1010 ¶¶ 74, 95). Petitioner

asserts that, because one purpose of the feet is to "secure" the on-body unit to the insertion device prior to insertion, a skilled artisan would have therefore been motivated, with a reasonable expectation of success, to provide recesses on the on-body electronics unit housing in order to securely engage the on-body electronics unit to the inserter. *Id.* (citing Ex. 1003 ¶ 74; Ex. 1010 ¶ 123).

Petitioner argues further that, to the extent Patent Owner points to Figure 18 of Raymond, and argues that it discloses a single annular recess around the periphery of the on-body unit, such argument cannot change the depiction of plural recesses in Raymond's Figures 29 and 30. Pet. 30. Furthermore, argues Petitioner, even if Raymond taught only a single annular recess, it would have been an obvious design choice to implement two spaced-apart plural recesses on the housing—one to engage the protrusions on each of the two arms taught by Raymond. *Id.* at 30–31 (citing Ex. 1003 ¶ 75; Ex. 1010, Figs. 18, 25–27).

Petitioner maintains that one of ordinary skill in the art would have recognized that there were only two possibilities for a system having arms with protrusions that engage some type of recess: (1) either the two arms engage different points of a single annular recess; or (2) each arm engages its own independent recess. *Id.* (citing Ex. 1003 ¶ 75). Petitioner asserts that a recess for each arm would provide a more secure fit between the inserter and on-body unit, and that Figures 29 and 30 show a recess for each arm, thus making it the better choice. *Id.* (citing *Perfect Web Tech., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331–32 (Fed. Cir. 2009) (holding that it would have been obvious to try one of three predicable solutions)).

Petitioner also argues that a skilled artisan would have been motivated to combine Stafford and Raymond. Pet. 21. Petitioner contends that Raymond improves upon a problem expressly identified by Stafford by preventing accidental injury when withdrawing the sharp needle from a subject. *Id.* (citing Ex. 1003 ¶ 51; Ex. 1009 ¶¶ 3, 22; Ex. 1010 ¶¶ 8, 104, 109, 127). Specifically, Petitioner notes that Stafford teaches a glucose sensor introducer with a "sharp tip" and expresses a desire to prevent both pre-insertion and post-insertion injuries, but proposes a guard segment for preventing only pre-insertion injuries. *Id.* at 21–22 (citing Ex. 1009 ¶¶ 2, 3, 21, 22, 49). Petitioner argues that Raymond describes a needle-based insertion device designed to "minimize the possibility of accidental needle sticks" and "provid[e] safe operation and disposal" by ensuring that the needle is only exposed during insertion. *Id.* at 22 (citing Ex. 1003 ¶ 51; Ex. 1010 ¶¶ 8, 104, 109, 127). Petitioner asserts that a person of ordinary skill in the art would have understood that, compared to Stafford's solution, which only guards against pre-insertion injuries, Raymond's improved solution prevents against both pre- and post-insertion injuries. *Id.* (citing Ex. 1003 ¶ 51). Petitioner further contends that Raymond also improves upon Stafford's insertion process by reducing pain and anxiety to the user that may be caused by exposed insertion needles. *Id.* (citing Ex. 1003 ¶ 52).

Finally, Petitioner argues that a person of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of Stafford and Raymond. Pet. 24 (citing Ex. 1003 ¶ 56). Petitioner contends that the interchangeability of insertion devices for cannulas and sensors was well known in the art. *Id.* (citing Ex. 1003 ¶ 57;

see also Pet. 10–11). A skilled artisan, argues Petitioner, could have easily adapted Raymond's cannula inserter for use with Stafford's on-body housing by, e.g., using a needle-like introducer that accommodated the sensor within, as also taught by Stafford.[11] *Id.*

Petitioner contends that, given the known interchangeability of inserter devices between infusion sets and analyte sensors and similar devices, a skilled artisan could have easily implemented the on-body electronics unit with recesses that engaged with the gripping arms, as taught by Raymond. Pet. 24.

3. Patent Owner's Preliminary Response

Patent Owner argues that "Petitioner's cited art does not disclose 'a plurality of recesses disposed on a periphery of the on body electronics unit.'" Prelim. Resp. 37–38. Patent Owner points to Petitioner's concession that Thomas fails to expressly disclose such a plurality of recesses, as claimed, and relies on Raymond's annular rim as meeting this requirement. *Id.* at 38–39 (citing Ex. 1010, Fig. 18). Patent Owner argues that this same argument has been advanced by Petitioner in, and rejected by, other tribunals, including the European Patent Office. *Id.* at 40–41 (citing Ex. 2001 ¶¶ 21.2, 21.5).

Patent Owner argues further that it would not have been obvious to have modified Raymond's design to create multiple recesses rather than one

[11] Petitioner also notes that the '335 patent states that its "inserter can be configured to insert various medical devices into the subject, such as for example, an analyte sensor, an infusion set, or a cannula." Pet. 24 (quoting Ex. 1001, col. 22, ll. 27–29).

because there was no need for it and doing so would serve only to make an already complex design needlessly more so. Prelim. Resp. 42. And, argues Patent Owner, although Petitioner tries, it cannot show any evidence of the prior art knowledge of a plurality of recesses, as claimed. *Id.* at 43–45.

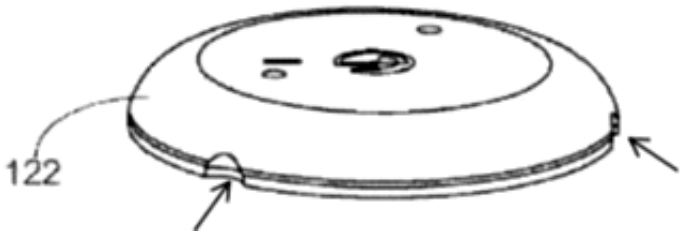
4. Analysis

Having reviewed Petitioner's arguments and the evidence of record as established at this stage of the proceeding, we conclude that Petitioner has failed to demonstrate a reasonable likelihood of success of establishing at trial that claim 1 of the '335 patent is unpatentable upon Ground 1.

Claim 1 recites, in relevant part:

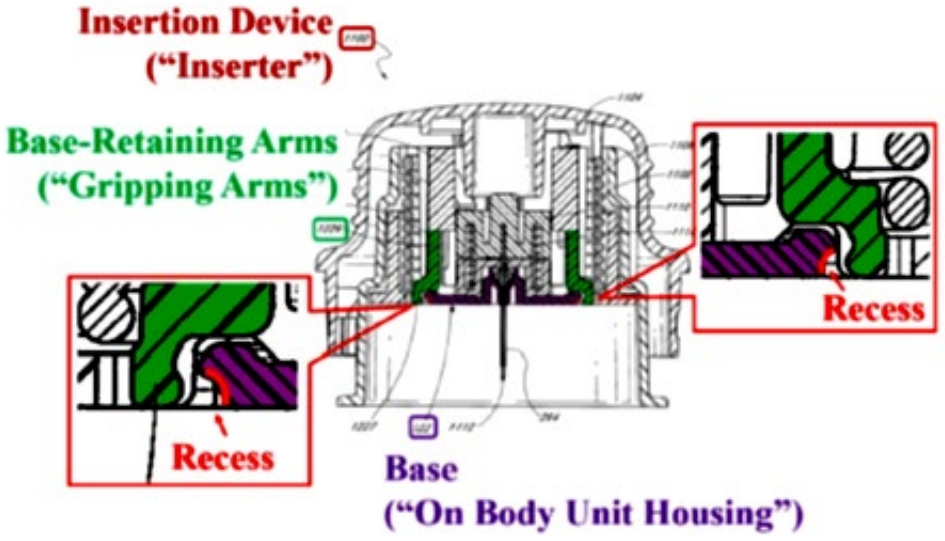
> an on body electronics unit housing comprising ***a plurality of recesses disposed on a periphery*** of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter.

Figure 17 of the '335 patent depicts an embodiment of on-body electronics unit housing 122, with the "plurality of recesses comprises a first recess in a spaced relation to a second recess," "disposed on a periphery of the on body electronics unit housing." Figure 17 of the '335 patent is reproduced below, with the first and second recesses indicated by arrows:



Annotated Figure 17 (detail) of the '335 patent, indicating with arrows the plurality of recesses on the periphery of the on-body electronics housing unit 122

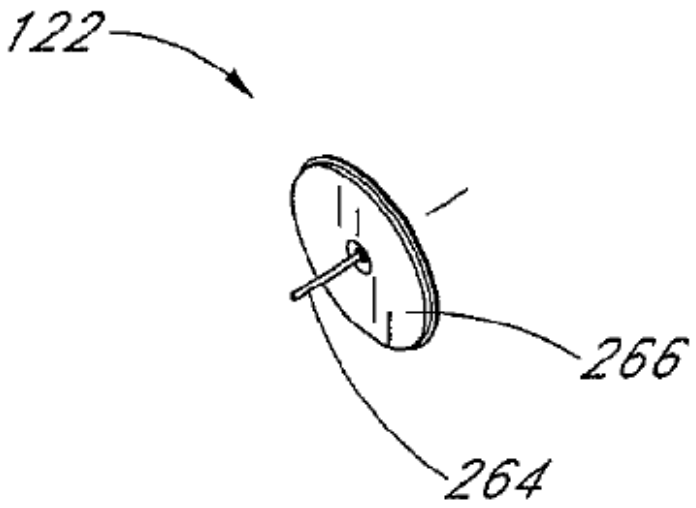
Petitioner relies upon Raymond as teaching this limitation of challenged claim 1. *See, e.g.*, Pet. 16–18. Petitioner equates base 122 of the infusion device of Raymond as functionally equivalent to the claimed on-body housing unit. *Id.* Petitioner acknowledges that Raymond does not expressly disclose a plurality of recesses distributed on the periphery of the on-body electronics housing unit, but points to Figure 29 of Raymond as teaching this limitation. *Id.* at 29. Petitioner's annotated version of Raymond's Figure 29 is reproduced again below:



Petitioner's annotated version of Figure 29 of Raymond

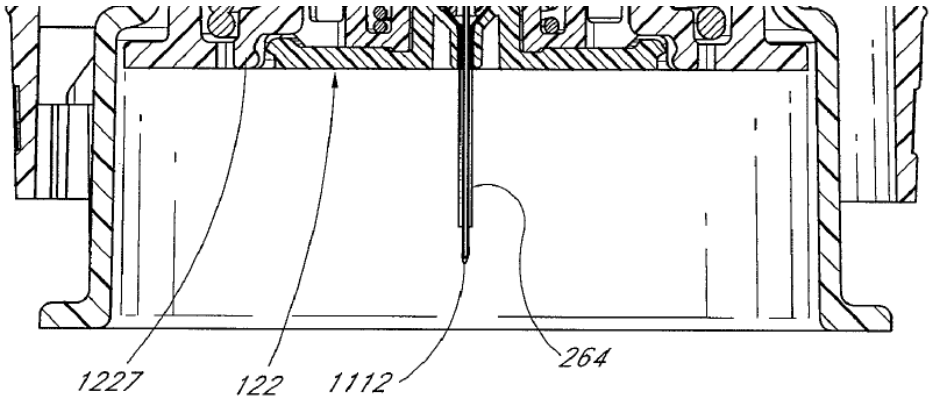
In particular, Petitioner points to the enlarged portions of its annotated Figure 29, arguing that a skilled artisan would have recognized that the portions of base 122 indicated in red on either side of base 122 constitute the plurality of recesses located on the periphery of the on-body electronics housing unit. Pet. 29.

We do not find this argument persuasive. Figure 29 is a "cross-sectional view,… of the insertion device" disclosed by Raymond. Ex. 1010 ¶ 55. Another view of base 122 is depicted in Raymond's Figure 18, a detail of which is reproduced below:



Detail of Figure 18 of Raymond showing base 122

As shown in Figure 18, base 122 of Raymond's device comprises a circular disk, with an annular ring on the proximal side. This view is consistent with the cross-sectional view of base 122 in Raymond's Figure 29, reproduced below:



Detail of Raymond's Figure 29 depicting a cross-sectional view of base 122

The annular ring of base 122, as depicted in Raymond's Figures 18 and 29 thus comprises, at most, a single recess encircling base 122 beneath the annular ring at the periphery of the base. As such, it neither teaches nor suggests "a plurality of recesses disposed on a periphery of the on-body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess," as required by challenged claim 1 of the '335 patent.

Petitioner's argument that Figures 20 and 30 of Raymond depicts plural recesses in Raymond's base 122 is based upon a false premise. *See* Pet. 37–38. The depiction of base 122 in these Figures is entirely consistent with the depiction of base 122 in Raymond's Figure 18 as having an annular ring with a single recess situated beneath its rim. With respect to Petitioner's argument that it would have been an obvious design choice to implement two spaced-apart plural recesses on the housing (see Pet. 38), neither Petitioner nor its Declarant, Dr. Fletcher, adduces any evidence beyond that conclusory statement. *Id.* at 38 (citing Ex. 1103 ¶ 70; Ex. 1110, Figs. 18, 25–27); Ex. 1003, 77. Petitioner makes no persuasive argument as

to why a skilled artisan would have substituted multiple recesses for a single annular ring, which seemingly serves the purpose of allowing base 122 to be held in position by base-retaining arms 1226. To the contrary, substituting multiple recesses in base 122 to engage retaining arms 1226, and ensuring that each retaining arm 1226 suitably engages each recess, would seem only to add needless complexity to the design, without producing a substantial benefit or improvement.

Petitioner argues further that other prior art references teach or suggest that "feet/protrusions like those taught by Raymond were regularly designed to engage corresponding recesses or notches on associated components, in order to retain the components in relative position to one another." S*ee* Pet. 30. In support of its contention, Petitioner points to Kovelman[12], Safabash[13], Bobroff[14], and Douglas[15].

We find this position to be no more persuasive than Petitioner's other position that Raymond teaches or suggests "a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess." Kovelman, Safabash, and Bobroff are all assigned to the same assignee and have overlapping listings of inventors. *See* Ex. 1018, codes (75), (73); Exs.

[12] Kovelman et al. (US 2004/0002682 A1, January 1, 2004) ("Kovelman"), Ex. 1018.

[13] Safabash et al. (US 7,207,974 B2, April 24, 2007) ("Safabash"), Ex. 1040.

[14] Bobroff et al. (US 2002/0022855 A1, February 21, 2002), ("Bobroff") Ex. 1042.

[15] Douglas (US 2005/0131346A1, June 16, 2005) ("Douglas"), Ex. 1057.

1040, 1042, *same*. All three references are directed to "[a]n insertion device for inserting at least a portion of at least one piercing member of an insertion set through the skin of a patient." Ex. 1040, Abstr.; *see also* Exs. 1018, 1042, *same*. All three references recite, word-for-word, the same description of what Petitioner alleges are "feet/protrusions [that] were regularly designed to engage corresponding recesses or notches on associated components." Pet. 30. By way of example, Kovelman teaches:

> The plunger head includes a safety lock mechanism to retain the insertion set against projection from the injector barrel. In one preferred form, the safety lock mechanism comprises at least one and preferably a pair of safety lock arms for engaging and retaining the insertion set when the plunger is retracted from a fully advanced position. Each safety lock arm includes a cam lobe for engaging an appropriately shaped recess on the insertion set to prevent release thereof from the plunger head, unless and until the plunger head is returned to the fully advanced position. In such fully advanced position, the shape of the cam lobe permits quick and easy separation of the injector from the insertion set with a minimal separation force.

Ex. 1018 ¶ 11; *see also* Ex. 1040, col. 2, ll. 45–57; Ex. 1042 ¶ 10.

Furthermore, each reference has identical illustrations depicting this aspect of the respective devices. For example, Figure 4 of Kovelman depicts recess 101, "defined between the hub 18 and housing 20 of the insertion set." A detail of Figure 4 of Kovelman is reproduced below:

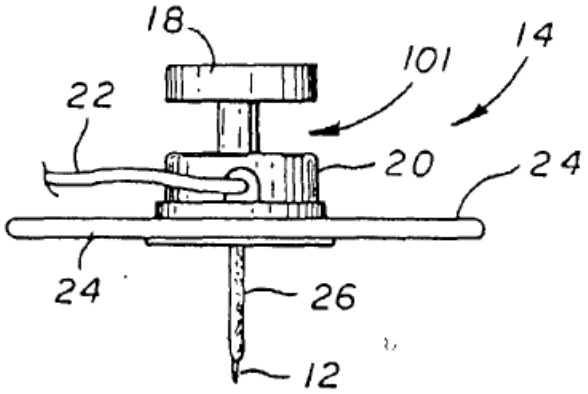


FIG. 4

Figure 4 (detail) depicting insertion set 14 with recess 101 between hub 18 and housing 20

See also Ex. 1040, Fig. 4; Ex. 1042, Fig. 4.

Figure 7 of all three references, reproduced below, depicts the insertion set 14 housed in the insertion device, with contoured lock fingers 100 "fitting into a recess 101 defined between the hub 18 and housing 20."

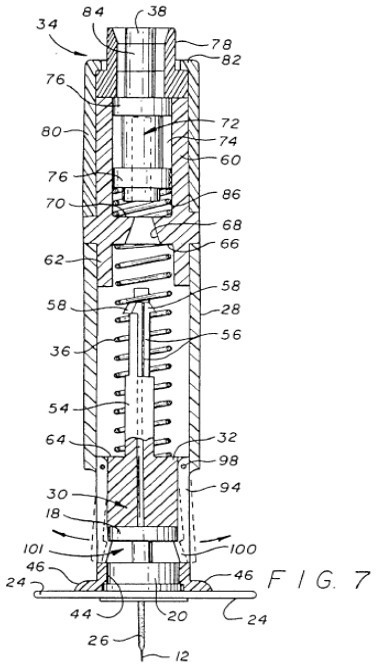


FIG. 7

Figure 7 of Kovelman depicting insertion set 114 housed in the insertion device

See also Ex. 1040, Fig. 7; Ex. 1042, Fig. 7.

It is readily apparent from the identical figures that, as with Raymond's base and ring discussed above, none of these references teach a "plurality of recesses disposed on a periphery of the on body electronics housing unit," as recited in challenged claim 1, but rather disclose a singular, circular recess between hub 18 and housing 20.

With respect to the remaining reference cited by Petitioner, Douglas teaches:

> The plunger head may optionally include a safety lock mechanism to retain the insertion set against projection from the inserter barrel. According to an embodiment, the safety lock mechanism comprises at least one safety lock arm(s) for engaging and retaining the insertion set when the plunger is retracted from a fully advanced position. Each safety lock arm may optionally include a cam lobe for engaging an appropriately shaped recess on the insertion set to prevent release thereof from the plunger head, unless and until the plunger head is returned to the fully advanced position. In such fully advanced position, the shape of the cam lobe may permit quick and easy separation of the inserter from the insertion set with a minimal separation force.

Ex. 1057 ¶ 15. This passage is strikingly similar to the passage of Kovelman, Safabash, and Bobroff quoted above. *See, e.g.*, Ex. 1018 ¶ 11. Moreover, Douglas provides no illustration of the cam lobe or its corresponding recess, and refers to "a" or "the" recess only in the singular sense. *See* Ex. 1057 ¶¶ 17, 21. Furthermore, and as depicted in Figure 7 of Kovelman above, which illustrates a very similar device (as described by both specifications), multiple arms engage a *single* recess positioned beneath hub 18. Petitioner points to no passages in Douglas that teach or suggest a

"*plurality of recesses* disposed on a periphery of the on body electronics housing unit," as recited in challenged claim 1 (emphasis added).

We also note that this issue has been litigated previously, in an Opposition proceeding before the Opposition Division of the European Patent Office ("EPO"), brought by Petitioner against a patent related to the '335 patent (EP 3 766 408 B1, the "'408 European patent"). *See* Prelim. Resp. 40; Ex. 2001. Like the '335 Patent, the claims in the '408 European patent recite, *inter alia*, an on-body electronics unit housing comprising '[a] plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprise a first recess in a spaced relation to a second recess." Ex. 2002, claim 1.

In the Opposition proceeding, Petitioner also argued that Raymond discloses a plurality of peripheral recesses on the housing of the on-body electronics unit. In its Preliminary Opinion, the Opposition Division rejected Petition's arguments in this respect:

> D10 [(Raymond)] does not appear to disclose any on-body electronics. Contrary to Opponent 1's [i.e., Petitioner's] position, however, it also seems not to disclose recesses on an on-body unit housing. Opponent 1 refers to Fig. 26 and 29 as showing recesses; however, feet 1227 of arms 1226 do not appear to engage base 122 at a plurality of recesses. Paragraph [0123] merely discloses that the feet clamp, grasp or otherwise engage the base, and the base is not shown to have recesses (see also Fig. 18). Rather, it appears that the feet grasp a rim on the base.

Ex. 2001 ¶ 21.2. The Opposition also rejected Petitioner's arguments concerning Kovelman:

> D1 [(Kovelman)] does not appear to disclose a plurality of recesses on an on-body unit housing, comprising a first recess in a spaced relationship to a second recess.
>
> Opponent 1 [(Petitioner)] refers to element 101 in Fig. 7 of D1 as recesses. What is referred to as recess 101 in D1 is, however, merely a single spacing between hub 18 and housing 20, compare Fig. 4.

Ex. 2001 ¶ 21.1.

Although we are in no manner bound by the Opinion of the Opposition Division of the EPO, we nevertheless, and for the reasons we have explained above, agree with their reasoning.

We conclude that Petitioner has not persuasively demonstrated that either Stafford or Raymond teaches or suggests the limitation of challenged claim 1 reciting:

> [A]n on body electronics unit housing comprising ***a plurality of recesses disposed on a periphery of the on body electronics unit housing***, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter.

Consequently, we conclude that Petitioner has failed to meet its burden of demonstrating a reasonable likelihood of success in showing at trial that challenged claim 1 is unpatentable.

5. Claims 2–4, 8, 9, and 11–27

Challenged claims 2–4, 8, 9, and 11–27 of the '335 patent all ultimately depend from challenged claim 1, which is the sole independent challenged claim. As such, each of claims 2–4, 8, 9, and 11–27 incorporate by reference the limitation of claim 1 reciting:

> [A]n on body electronics unit housing comprising ***a plurality of recesses disposed on a periphery of the on body electronics unit housing***, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter.

See Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1357 (Fed. Cir. 2007) (holding that "[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers" (quoting 35 U.S.C § 112, ¶ 4 (2000)).

Because Petitioner has failed to demonstrate a reasonable likelihood of success in demonstrating at trial that challenged claim is unpatentable on Ground 1, Petitioner similarly fails to meet the same burden with respect to challenged dependent claims 2–4, 8, 9, and 11–27.

C. Ground 2: Obviousness under 35 U.S.C. § 103(a) of Claims 1–4, 8, 9, and 11–27 over Stafford (Ex. 1009), Raymond (Ex 1010), and Turner (Ex. 1011)

1. Overview of the Prior Art

a. Turner

Turner is U.S. Appl. 2007/0135774 Al, published on June 14, 2007, and is prior art to the '335 patent. Ex. 1011, codes (10), (43).

Turner is directed to: "Fluid delivery devices, systems, and methods." Ex. 1011, Abstr. Specifically, Turner teaches that its invention:

> [M]ay be used to deliver fluid such as insulin to users such as people with diabetes. Some embodiments of the present fluid delivery devices may be configured to be worn for an extended period of time (e.g., multiple days) and allow a user to inject a fluid (such as a physician-prescribed drug) into the user's body

without the need to repeatedly puncture the user's skin with a needle.

Ex. 1011 ¶ 6. Turner teaches that certain embodiments of its invention include, broadly, a body, a cannula, a needle guide, and a septum, and that the body may be made from one or more pieces. *Id.* ¶ 7.

Figure 9 of Turner depicts the base of an embodiment of the fluid delivery system of Turner, and is reproduced below:

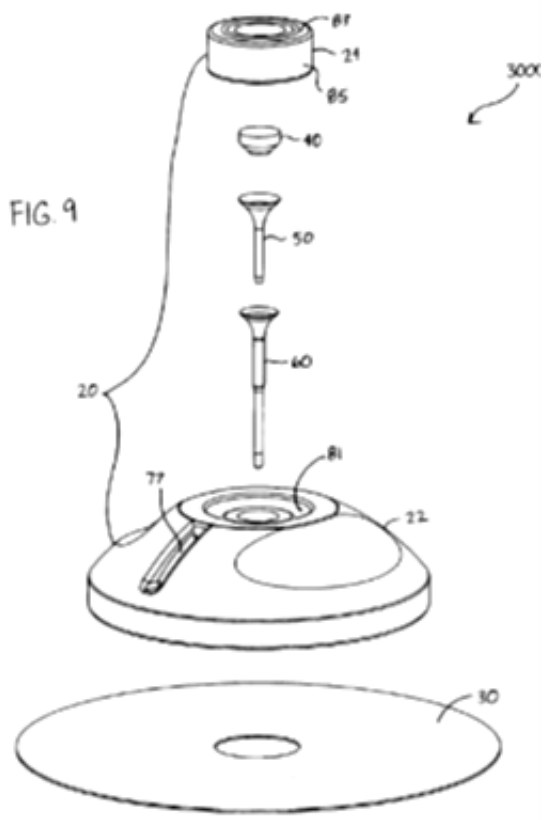
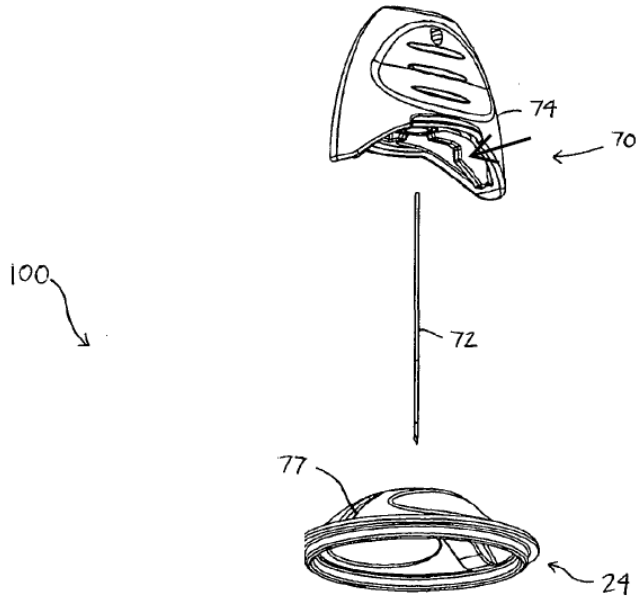


Figure 9 of Turner is a perspective, exploded view of its fluid delivery system including body 20

Turner discloses that, in this embodiment, body 20 includes rotation-restricting recesses 77. Ex. 1011 ¶ 102. Figure 2B of Turner (reproduced below) illustrates how:

> Body **20** and insertion device **70** may be configured such that insertion device **70** cannot rotate with respect to body **20** when fully inserted in body **20**. One manner of achieving this configuration comprises providing hub **74** with rotation-restricting protrusions **71**[16], which extend in a downstream or downward direction from the main portion of insertion device hub **74**, and by providing cap element **24** of body **20** with rotation-restricting recesses **77**.

Id. ¶ 69.



Annotated detail of Figure 2B of Turner showing rotation-restricting protrusions (unlabeled arrow) and rotation restricting recesses 77

Figure 3 of Turner illustrates how rotation-restricting protrusions 71 and rotation restricting recesses 77 fit together to prevent relative rotation of insertion device 70 and body 20 (*see* Figure 9 above):

[16] Rotation restriction protrusions 71 are not labeled in Turner's Figure 2B, but are indicated by the unlabeled arrow.

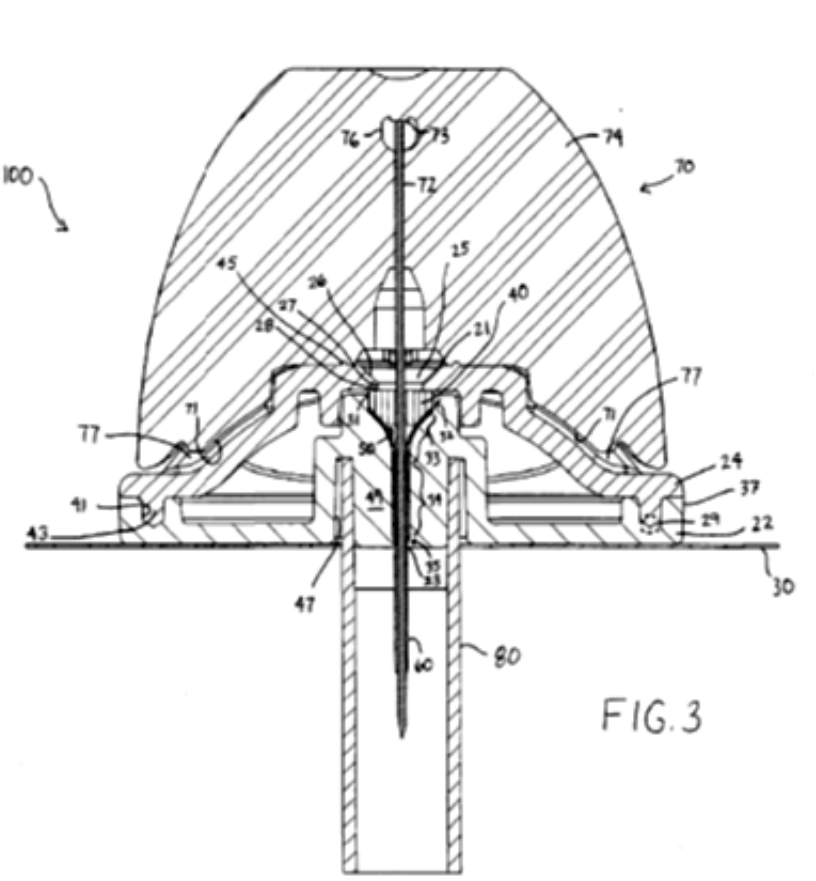


Figure 3 of Turner is a cross sectional view depicting rotation-restricting protrusions 71 and rotation restricting recesses 77 fitted together

See also Ex. 1011 ¶¶ 69–71.

2. Petitioner's arguments

Petitioner makes the same arguments concerning Stafford and Raymond that were presented and discussed above with respect to Ground 1. Pet. 25–34. Additionally, Petitioner argues that Turner demonstrates the obviousness of adding plural recesses to the periphery of the housing to beneficially prevent relative rotational movement between the housing and the inserter. *Id.* at 25 (citing Ex. 1003 ¶ 60; Ex. 1011 ¶ 69). According to

Petitioner, Turner provides express teachings on the use of "rotation-restricting recesses" that "prevent rotation of the insertion device relative to [the on-body unit]," thus confirming a benefit of this type of feature. *Id.* (alteration in original). Petitioner contends that, given the motivation to avoid relative movement between the housing and the inserter, and Turner's express teachings of plural recesses, a person of ordinary skill in the art would have naturally implemented the housing, as taught by Stafford and Raymond, with plural recesses that engage corresponding portions of the inserter. *Id.* (citing Ex. 1003 ¶ 60).

With specific reference to limitation [1.5] of claim 1, Petitioner argues that Turner teaches the utility and desirability of a plurality of rotation-restricting recesses configured to engage a corresponding plurality of rotation-restricting protrusions. Pet. 31–32 (citing Ex. 1011 ¶ 69). Petitioner contends that a skilled artisan, comprehending the teachings of Turner, would have been motivated to implement similar plural rotation-restricting recesses on the periphery of Stafford's housing to prevent rotation between the housing as taught by Stafford and the inserter as taught by Raymond. *Id.* at 32 (citing Ex. 1003 ¶ 77).

Moreover, Petitioner contends that Patent Owner effectively admitted that a skilled artisan would have been motivated to include complementary recesses to mate with corresponding protrusions, as taught by Turner. Pet. 32. Petitioner asserts that, in a filing in an action in the Munich (Germany) District Court I related to the '408 European patent, Patent Owner submitted an annotated version of Turner's Figure 3. *Id.* (citing

Ex. 1065, 66). Patent Owner's annotated version of Turner's Figure 3 is reproduced below:

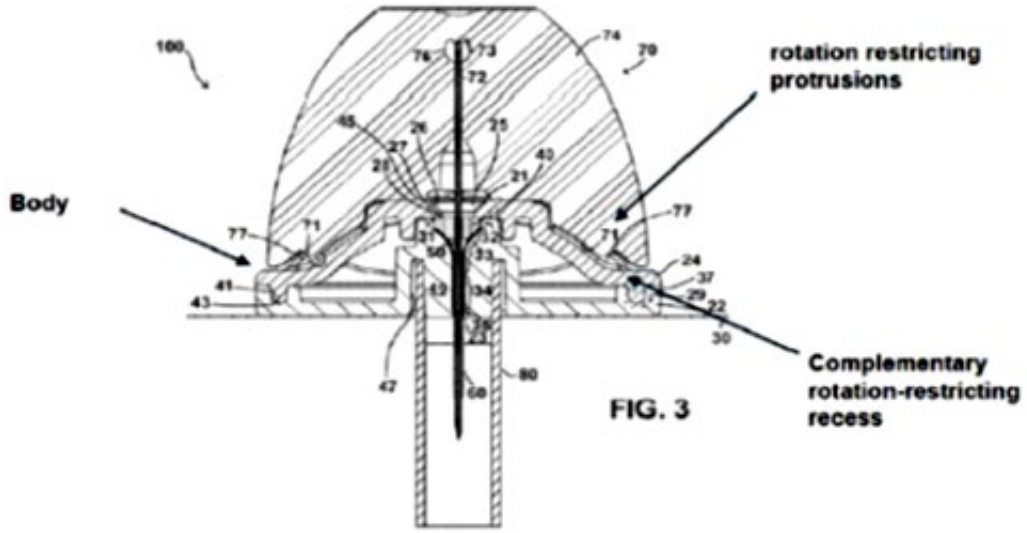


Figure 3 of Turner as annotated by Patent Owner

Pet. 32.

Petitioner asserts that Patent Owner contended in that German proceeding that "the skilled person would transfer the protrusions for preventing rotation of the hub 74 disclosed in [Turner] to a CGM [continuous glucose monitoring] device." Pet. 33 (quoting Ex. 1065, 67; citing *Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367, 1376 (Fed. Cir. 2022)) (first alteration in original).

Therefore, argues Petitioner, because Patent Owner contended that a person of ordinary skill in the art would have been motivated to implement Turner's rotation-restricting teachings on a CGM device, a skilled artisan would have been motivated to implement rotation-restricting features on the periphery of the housing taught by Stafford. Pet. 33.

3. Patent Owner's Preliminary Response

Patent Owner argues that, even assuming that a person of ordinary skill in the art would have combined Stafford's stand-alone glucose sensor assembly with Raymond's infusion device and Turner's fluid delivery device, Petitioner's argument fails because Turner does not disclose *peripheral* on-body unit housing recesses. Prelim. Resp. 52. Patent Owner asserts that, rather than being located on the periphery, anti-rotation recesses 77 of Turner extend in a vertical direction on the upper surface of Turner's body 20, and closer to the center than the periphery of the device. *Id.* Patent Owner contends that Turner's body 20 upper-surface recess locations are not mere happenstance; rather, they are designed to interact with vertically-extending, rotation restriction protrusions 71 from Turner's needle hub 74. *Id.* at 53. Patent Owner argues that, because the periphery of Turner's on-body unit extends beyond the width of needle hub 74, Turner's recesses cannot be on the periphery of the on-body unit. *Id.* Moreover, argues Patent Owner, because rotation-restricting protrusions 71 of Turner's needle hub 74 extend vertically "in a downstream or downward direction" from an interior part of the hub, Turner's anti-rotation recesses 77 must be positioned on body 20's upper surfaces, away from the periphery. *Id.* at 54 (quoting Ex. 1011 ¶ 69).

Patent Owner also disputes Petitioner's argument that a skilled artisan would have found it obvious to add Turner's rotation-restriction recesses 77 to secure Stafford's data processing unit housing within Raymond's inserter. Prelim. Resp. 55 (citing Pet. 11–12, 19, 30). Patent Owner contends that this "securing" argument fails for multiple reasons. *Id.*

First, argues Patent Owner, Raymond's pre-existing inserter already secures its on-body unit without such recesses. Prelim. Resp. 55 (citing Ex. 1010 ¶ 123). Patent Owner notes that Petitioner and its expert, Dr. Fletcher, both admit this fact. *Id.* (citing Pet. 16; Ex. 1003 ¶ 41). Therefore, Patent Owner argues, Petitioner's Turner-based "securing" argument fails for similar reasons as Petitioner's position based on the combination of Stafford and Raymond. *Id.* Patent Owner contends that, other than *via* improper hindsight, there was no need to add Turner's recesses to a device resulting from a combination of Stafford and Raymond for "securing" purposes, especially given that adding Turner's elements would add unnecessary further complexity to Raymond's already-complex assembly. *Id.*

Additionally, argues Patent Owner, Petitioner's Turner-based "securing" argument makes little sense because Turner's recesses are not used for securing an on-body unit within an inserter via detachable engagement. Prelim. Resp. 56. Rather, Patent Owner contends, Turner's cited rotation-restricting recesses 77 serve to prevent rotation between Turner's needle hub 74 and body 20. *Id.* (citing Ex. 1011 ¶ 69). Patent Owner notes that Turner further teaches that its rotation-restricting recesses 77 are optional, confirming that they are not responsible for "securing" body 20. *Id.* Rather, Patent Owner argues, Turner teaches that its needle hub 74 is secured to body 20 *via* a friction fit between the needle (coupled to the needle hub) and the septum 40 of the body 20. *Id.* at 56–57 (citing Ex. 1011 ¶ 99).

In support of this contention, Patent Owner again points to the EPO Opposition, wherein that tribunal found:

> Opponent 2 [Petitioner's German-related entity] argues that D21 [Turner] discloses in Fig. 2A and paragraph [0069] protrusions (71) on the insertion device (70) [i.e., the needle hub coupled to the needle] that extend to engage recesses (77) in the cap element (24) of body (20). According to [Turner] however, the protrusions and recesses serve to prevent rotation of the insertion device (70) [needle hub with needle] relative to the body (20). In contrast, the gripping arms and recesses according to granted claim 1 serve to hold the on-body housing (322) in place and to maintain the proper height location of the on-body housing (322), see paragraph [0258] of the original application and granted claim 1: " … gripping arms configured to be engaged with a corresponding recess … when the on body electronics unit is in the proximal position"). It thus appears that the skilled person would not consult [Turner] when seeking means for holding the on-body unit housing of D14 [WO 2010/091005 A1] in place.

Prelim. Resp. 58 (quoting Ex. 2001 ¶ 21.3 (underlining and alterations in original)).

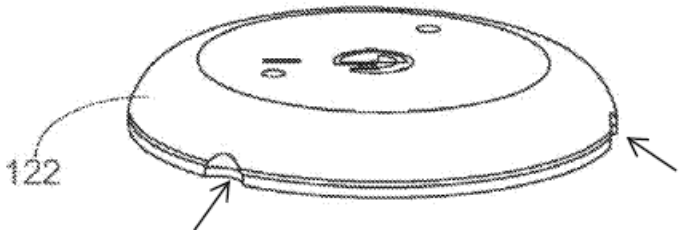
Patent Owner argues that Turner's rotation-restricting recesses 77 do not achieve the purpose of "detachably engag[ing] with the inserter," as recited in claim 1. Prelim Resp. 58–59 (quoting Ex. 1001, claim 1). Patent Owner further asserts that Petitioner fails to cite any reason why a person of ordinary skill in the art would have wanted to prevent rotation between the on-body unit and inserter of the Stafford and Raymond combination. *Id.* at 59. Patent Owner argues that Turner's rotation-restricting protrusions 71 and recesses 77 do not serve the purpose of detachably engaging with the inserter, as required by the claim. *Id.* at 59–60.

4. Analysis

Having considered the parties' arguments and the evidence of record as established at this stage of the proceeding, we conclude that Petitioner has not established a reasonable likelihood of demonstrating at trial that claims 1–4, 8, 9, and 11–27 of the '335 patent are unpatentable over the combination of Stafford, Raymond, and Turner.

In Sections IV.B.3 and IV.B.4 above, we explained why Petitioner's arguments are insufficient to establish a reasonable likelihood that the challenged claims were obvious over the combination of Stafford and Raymond. Specifically, we concluded that Petitioner's arguments were insufficient to establish a reasonable likelihood that the combined references taught or suggested the limitation of claim 1 reciting "a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter." Our above reasoning is also valid with respect to Ground 2. The question remaining before us with respect to Ground 2, then, is whether Petitioner's arguments relating to Turner cure the deficiencies of Stafford and Raymond with respect to the disputed limitation.

We conclude that they do not. Claim 1 of the '335 patent requires "an on body electronics unit housing comprising a plurality of recesses *disposed on a periphery of the on body electronics unit housing*" (emphasis added). Figure 17 of the '335 patent, although it does not necessarily limit the challenged claims, depicts recesses disposed on a periphery of an on-body electronics housing unit:



Annotated Figure 17 (detail) of the '335 patent, indicating with arrows the plurality of recesses on the periphery of the on-body electronics housing unit 122

The Specification of the '335 patent further describes the peripheral recesses of the on-body electronics housing unit:

> [G]ripping arms **3762** [of medical device carrier **3730**] are provided with engagement boss **3764** which are configured to engage with *corresponding recesses **3766** provided on the side walls of the on body housing **322***. Such engagement of the recesses **3766** with the gripping arms **3762** maintains the proper height location of the on body housing **322**.

Ex. 1001, col. 44, ll. 9–14 (emphasis added). Figure 135 of the '335 patent, reproduced below, illustrates a spatial relationship between gripping arms 3762 with engagement bosses 3764 of medical device carrier 3730 and corresponding recesses 3766 of on-body electronics housing unit 322:

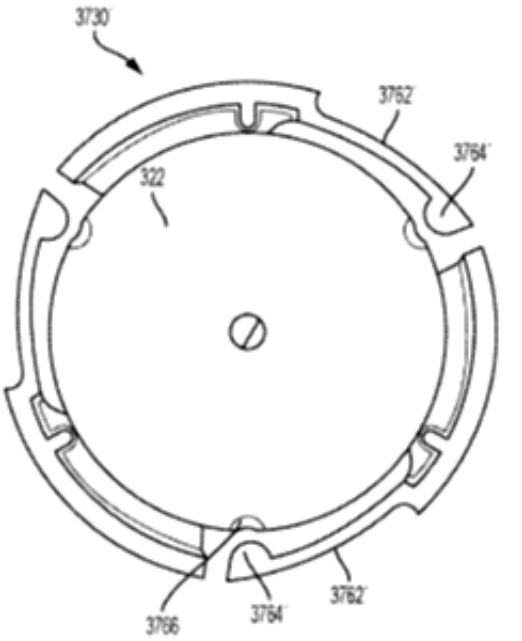


FIG. 135

Figure 135 of the '335 patent is a top-down view illustrating the relationship between engagement arms 3762 with engagement bosses 3764 and recesses 3766 located on the side wall of the on-body electronics housing unit 322.

Both the text and Figures of the '335 patent above, illustrate claim 1's limitation reciting "recesses disposed on a periphery of the on body electronics unit housing." Ex. 1101, col. 44, ll. 10–11. These peripheral recesses, mounted on the circumference of the on-body housing, are substantially different from what is disclosed in the prior art combination cited by Petitioner and, furthermore, serve an entirely different purpose.

Turner's rotation-resisting recesses 77 are not located on the peripheral edge of its body 20, such that they can be engaged to hold the on-body housing properly positioned within the device. Instead, they are disclosed as being located upon the upper surface of body 20, between its

central axis and its edge, and are configured to receive rotation-resisting protrusions 71 of insertion device 70. This placement of rotation-resisting recesses 77 is depicted in Figure 9 of Turner, which is reproduced again below:

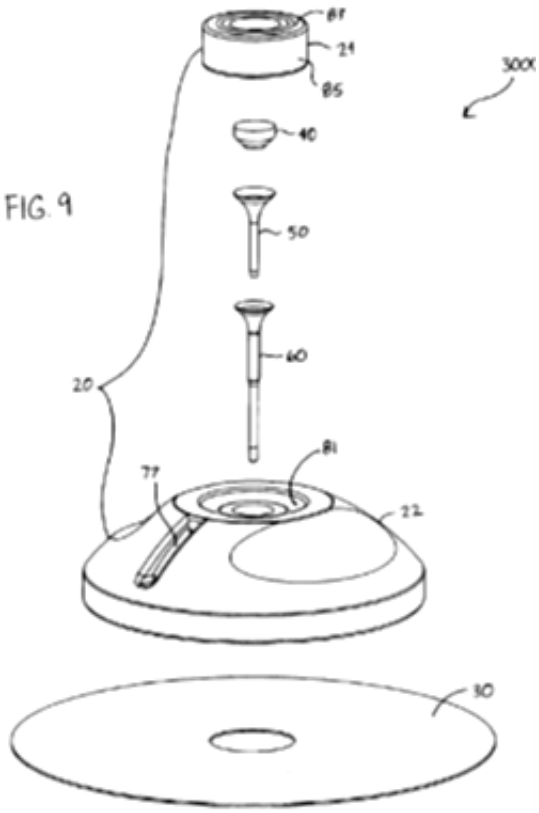


Figure 9 of Turner is a perspective, exploded view of its fluid delivery system including body 20 and rotation-restricting recesses 77

We therefore find that Turner does not teach or suggest the limitation of challenged claim 1 reciting "an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing."

We further conclude that Petitioner provides no persuasive reason why a person of ordinary skill in the art would have been motivated to alter

the location of Turner's rotation-resisting recesses 77 from the upper surface of body 20 to the periphery of body 20, because Turner and the '335 patent teach that their respective recesses serve different functions. Turner teaches that:

> Body **20** and insertion device **70** may be configured such that insertion device **70** cannot rotate with respect to body **20** when fully inserted in body **20**. One manner of achieving this configuration comprises providing hub **74** with rotation-restricting protrusions **71**, which extend in a downstream or downward direction from the main portion of insertion device hub **74**, and by providing cap element **24** of body **20** with rotation-restricting recesses **77**. When insertion device **70** is fully inserted in body **20**, as shown in FIG. **3**, at least a portion of each protrusion **71** extends into each recess **77** such that the recess side walls interfere with the protrusions to prevent rotation of the insertion device relative to body **20**.

Ex. 1101 ¶ 69. For the reader's convenience, annotated Figure 3 of Turner is reproduced again below:

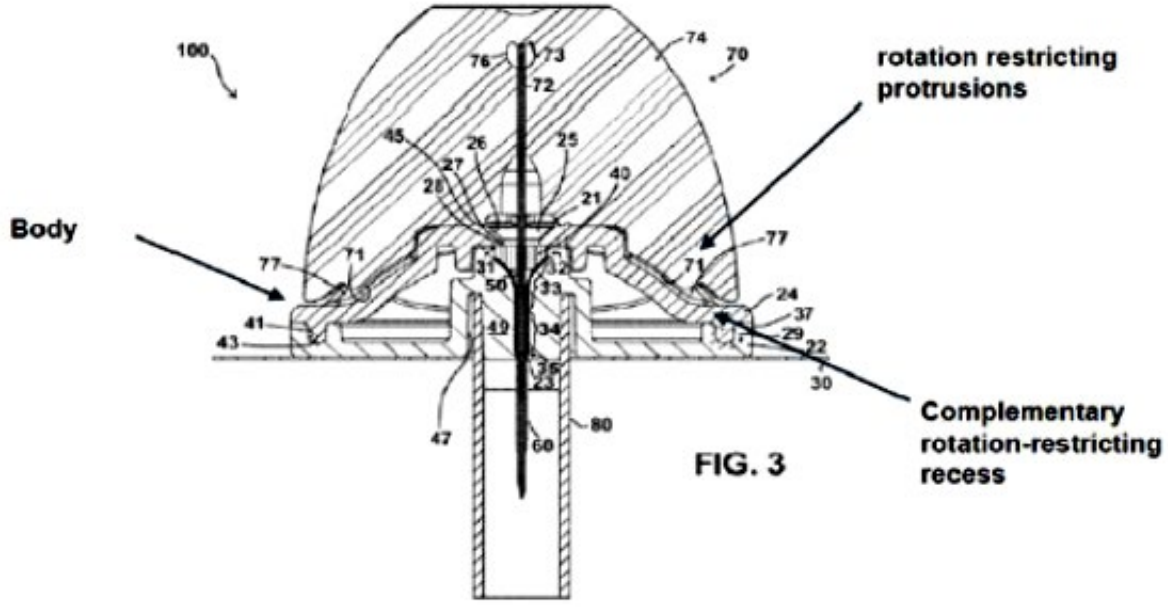


Figure 3 of Turner as annotated by Patent Owner

By contrast, the '335 patent discloses that recesses 3766 are configured to engage with engagement bosses 3764 of gripping arms 3762 to "maintain[] the proper height location of the on body housing 322" within the interior of its insertion device. Ex. 1001, col. 44, ll. 13–14.

We therefore conclude that Petitioner has failed to meet its burden of demonstrating a reasonable likelihood of success at trial in showing that claim 1 of the '335 patent is unpatentable as being obvious over the combination of Stafford, Raymond, and Turner. Furthermore, because challenged dependent claims 2–4, 8, 9, and 11–27 of the '335 patent all depend, either directly or indirectly, from claim 1, and incorporate by reference all of the limitations of claim 1, we conclude that Petitioner has similarly not demonstrated a reasonable likelihood of prevailing at trial with respect to these claims. *See Monsanto*, 503 F.3d at 1357.

D. Grounds 3–8

Petitioner's Grounds 3–8 challenge the patentability of dependent claims 16 (Grounds 3–6) or 17 and 18 (Grounds 7–8) as being obvious over Stafford and Raymond (Grounds 3, 5, 7), or Stafford, Raymond, and Turner (Grounds 4, 6, 8), in addition to references (Say, Bickoff, Shah) challenging the additional limitations of these dependent claims. *See* Section II.C above. Petitioner does not attempt to make up for the deficiencies of the Stafford, Raymond, and Turner combination with respect to claim 1, which we discuss above, by relying on the teachings of any additional prior art reference. Because each of claims 16–18 ultimately depend from independent challenged claim 1, and therefore incorporate the limitations of

that independent claim (*see Monsanto*, 503 F.3d at 1357), and because we conclude that Petitioner fails to demonstrate a reasonable likelihood that claim 1 is unpatentable over Stafford and Raymond (Ground 1), or Stafford, Raymond, and Turner (Ground 2), we similarly conclude that Petitioner is not reasonably likely to demonstrate at trial that challenged claims 16–18 are unpatentable under Grounds 3–8.

V. CONCLUSION

For the reasons we have explained, we conclude that Petitioner has failed to meet its burden of demonstrating a reasonable likelihood of prevailing in demonstrating that challenged claims 1–4, 8, 9, and 11–27 of the '335 patent are unpatentable under any of Grounds 1–8.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED, pursuant to 35 U.S.C. § 314(a), that the Petition for *inter partes* review of the challenged claims of U.S. Patent 11,266,335 B2 is DENIED with respect to all grounds in the Petition; and

FURTHER ORDERED that no *inter partes* review is instituted.

For PETITIONER:

Andrew Mason
Alexa Johnston
Michael Loy
Todd Siegel
Derrick Toddy
John Vandenberg
KLARQUIST SPARKMAN, LLP
Andrew.mason@klarquist.com
Alexa.johnston@klarquist.com
Michael.lo@klarquist.com
Todd.siegel@klarquist.com
Derrick.toddy@klarquist.com
John.vandenberg@klarquist.com

For PATENT OWNER:

Peter J. McAndrews
David Z. Petty
Michael J. Carrozza
MCANDREWS, HELD & MALLOY, LTD.
pmcandrews@mcandrews-ip.com
dpetty@mcandrews-ip.com
mcarrozza@mcandrews-ip.com