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Paper No. 13
Date: September 1, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.,
Petitioner,

v.

FACET TECHNOLOGIES, LLC,
Patent Owner.

IPR2023-00713
Patent 8,840,635 B2

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

TARTAL, *Administrative Patent Judge*.

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

I. INTRODUCTION

LifeScan, Inc. ("Petitioner")[1] filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1, 4, and 9–15 of U.S. Patent No. 8,840,635 B2 (Ex. 1001, "the '635 patent"). Paper 1 ("Pet."). Petitioner concurrently filed a petition in another proceeding requesting *inter partes* review of claims 1–3, 5–8, 14, and 16–18 of the '635 patent on different grounds. *LifeScan, Inc. v. Facet Technologies, LLC*, IPR2023-00712, Paper 1 (PTAB March 20, 2023) ("the '712 Petition"). Petitioner also filed a Ranking and Explanation for Two Petitions requesting that we consider whether to institute review based on the '712 Petition prior to considering the Petition in this proceeding. Paper 3 ("Ranking"). In IPR2023-00712 we granted the '712 Petition and instituted an *inter partes* review. IPR2023-00712, Paper 13 (PTAB September 1, 2023).

Facet Technologies, LLC ("Patent Owner")[2] filed a Preliminary Response. Paper 9 ("Prelim. Resp."). In its Preliminary Response, Patent Owner states that it disclaimed claims 1–5, 9, and 10 of the '635 patent, which includes claims 1, 4, 9, and 10 challenged by Petitioner in this proceeding. *Id.* at 7 n.5 (citing Exs. 2112, 2120 (collectively, the "Disclaimer"); 37 C.F.R. § 42.107(e)). Patent Owner also filed a Response to Petitioner's Ranking and Explanation. Paper 10 ("Ranking Response").

For the reasons provided below, and based on the circumstances present here, we find a second petition challenging claims of the same patent

[1] Petitioner identifies Asahi Polyslider Company Ltd. as an additional real party in interest. Pet. 1.
[2] Patent Owner identifies Facet Holdings Corporation as an additional real party in interest. Paper 5, 1.

is not warranted and exercise discretion under 35 U.S.C. § 314(a) to deny institution of an *inter partes* review in this proceeding.

II. BACKGROUND

A. The '635 Patent

The '635 patent, titled "Lancets with Improved Coupling Features and Sterility Caps," issued on September 23, 2014, from U.S. Patent Application No. 13/675,209, filed November 13, 2012. Ex. 1001, codes (21), (22), (45), (54). The '635 patent also refers back to Provisional Application No. 61/084,456, filed July 29, 2008. *Id.* at code (60).

The '635 patent "relates generally to the field of medical devices, and more particularly to lancets and lancing devices for blood sampling and testing." *Id.* at 1:17–19. The '635 patent explains as follows:

> [l]ancets typically comprise a sharp metal tip in the form of a needle or blade. The needle or blade is typically embedded in a plastic body that has a size and shape configured for releasable engagement with the receiver or lancet carrier of a lancing device. The sharp tip of the lancet is commonly embedded in a removable plastic cap to maintain sterility and prevent inadvertent sticks prior to use. The endcap may be replaceable onto the lancet after use to re-cover the sharp lancet tip for safety and hygienic purposes.

Id. at 1:43–52. According to the '635 patent, one aspect of "the invention relates to a protective sterility cap for a lancet, the sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, and a gripping handle portion extending from the primary sheath." *Id.* at 2:21–25.

Figure 1B of the '635 patent is reproduced below.

FIG. 1B

Figure 1B of the '635 patent depicts an example of a lancet according to one embodiment. *Id.* at 2:50–51. Lancet 10 includes body portion 12 having thickness T and lancet tip 14 projecting from one end thereof. *Id.* at 3:32–38.

Figure 5A of the '635 patent is reproduced below.

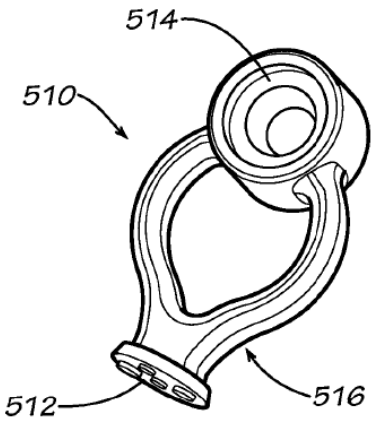

FIG. 5A

Figure 5A of the '635 patent depicts an example of a lancet endcap according to one embodiment. *Id.* at 2:58–59. Protective sterility cap 510 includes primary sheath portion 512 for receiving and protecting the sharp tip of an unused lancet. *Id.* at 6:1–9. Secondary sheath portion 514 is for receiving and protecting the sharp tip of a used lancet. *Id.* Handle portion 516 extends between primary sheath 512 and secondary sheath 516 and assists in removal and replacement of the cap from a lancet. *Id.*

Figure 5D of the '635 patent is reproduced below.

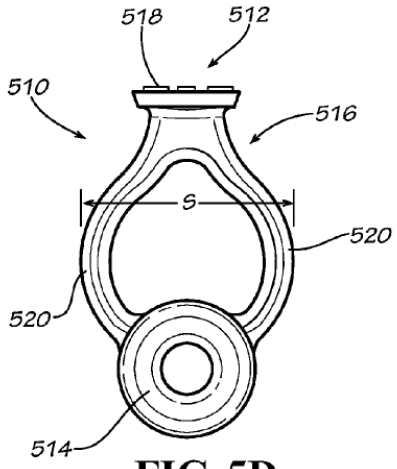

FIG. 5D

Figure 5D of the '635 patent depicts another view of protective sterility cap 510 shown in Figure 5A. *Id.* at 5:66–6:1. Handle portion 516 has a forked split configuration with first and second arms 520 transversely spaced apart from one another and an open center portion therebetween. *Id.* at 6:49–52. The '635 patent explains that the forked arrangement provides handle 516 with a greater width, which allows a user to easily twist the endcap during removal from a lancet. *Id.* at 6:52–54. According to the '635 patent, lateral span "S" of handle portion 516 is "at least about 1.5 times, and more preferably at least about 2 times the diameter or thickness of the lancet body. *Id.* at 6:56–58.

B. Illustrative Claim

In the Petition, Petitioner asserts that claims 1, 4, and 9–15 of the '635 patent are unpatentable. Pet. 4. Patent Owner disclaimed claims 1–5, 9, and 10 of the '635 patent, which includes claims 1, 4, 9, and 10 challenged by Petitioner in this proceeding. Prelim. Resp. 7 n.5. Claims 11–13 each depend, directly or indirectly, from disclaimed claim 9, and thus incorporate the subject matter of claim 9. Ex. 1001, 9:11–21.

Claim 14 is independent. *Id.* at 9:22–10:11. Claim 15 depends directly from independent claim 14. *Id.* at 10:13–14.

Claim 11 is illustrative of the claimed subject matter at issue and is reproduced below, along with disclaimed independent claim 9, from which claim 11 depends.

> 9. A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet, and wherein the gripping handle portion comprises at least one open loop.

Id. at 8:64–9:7.

> 11. The protective sterility cap of claim 9, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

Id. at 9:11–15.

C. Asserted Grounds of Unpatentability

In the Petition, Petitioner asserts that claims 1, 4, and 9–15 of the '635 patent are unpatentable. Pet. 4. As noted above, after the Petition was filed, Patent Owner explained that it disclaimed claims 1–5, 9, and 10 of the '635 patent. Prelim. Resp. 7 n.5 (citing Exs. 2112, 2120). Accordingly, we may only institute *inter partes* review based on Petitioner's allegations directed to claims 11–15. *See* 37 C.F.R. § 42.107(e)) (stating that "[n]o *inter partes* review will be instituted based on disclaimed claims").

Petitioner asserts the following grounds directed to claims 11–15:

Claims Challenged	35 U.S.C. §[3]	References/Basis
11–15	103(a)	Coe,[4] Sakata[5]
11–15	103(a)	Coe, Starnes[6], One Touch[7]
11–15	103(a)	Sakata, Morita[8]

Pet. 4. Petitioner relies on the supporting Declaration of Joel Delman, dated March 20, 2023. Ex. 1103. Patent Owner relies on the Declaration of John M. Collins, dated June 25, 2023. Ex. 2101.

D. Related Proceedings

The Parties identify the '635 patent as a subject of *Facet Technologies, LLC v. LifeScan, Inc.*, C.A. No. 22-cv-01717 (C.D. Cal.), filed on March 15, 2022. Pet. 1; Paper 5, 1. Petitioner also filed a petition challenging claims 1–3, 5–8, 14, and 16–18 of the '635 patent in IPR2023-00712. Paper 3, 1; Paper 5, 1.

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[3] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. For purposes of this Decision, we apply the pre-AIA version of § 103 here because the earliest provisional application identified in the '635 patent was filed before the effective date of the AIA and Petitioner does not currently challenge this priority date. *See* Ex. 1001, code (60). We note that our analysis would not change under the AIA version of § 103.

[4] US 5,207,699, issued May 4, 1993 (Ex. 1106, "Coe").

[5] JP 2005-168634, published June 30, 2005 (Ex. 1107, "Sakata"). Pages 1–8 of Exhibit 1107 provide an English translation of the original Japanese document, which appears on pages 10–17 of the exhibit.

[6] US 2007/0162064 A1, published July 12, 2007 (Ex. 1108, "Starnes").

[7] One Touch Basic Complete Diabetes Monitoring System Owner's Booklet (Ex. 1110, "One Touch").

[8] JP H5-285127, published Nov. 2, 1993 (Ex. 1109, "Morita"). Pages 1–10 of Exhibit 1109 provide an English translation of the original Japanese document, which appears on pages 11–19 of the exhibit.

III. ANALYSIS

Below we briefly summarize the references relied upon by Petitioner, then turn to whether discretionary denial under 35 U.S.C. § 314(a) is warranted, which we find to be dispositive for purposes of this Decision.

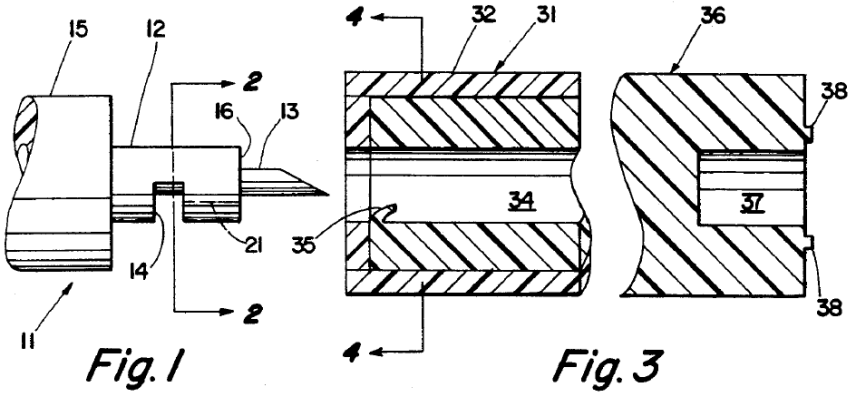
A. Overview of Cited References

In challenging the '635 patent in this proceeding, Petitioner relies on Coe, Sakata, Starnes, One Touch, and Morita, each of which we briefly summarize in relevant part below. *See* Pet. 3–4.

1. Summary of Coe (Ex. 1106)

Coe "relates to a blood lancet extraction and disposal assembly for use with an automatic lancet device of the type commonly used for taking skin capillary blood samples." Ex. 1106, 1:11–14. Coe states that there is "a significant need for an extraction and closure member for lancets which will effectively cover the lancet tip, maintain sterility, if necessary, and minimize the risk of accidental puncture wounds both during and after removal of the lancet from an automatic lancet device." *Id.* at 3:9–14.

Figures 1 and 3 of Coe are reproduced below.



Figures 1 and 3 of Coe provide a side cross-section view of a lancet according to a preferred embodiment. *Id.* at 3:49–51, 55–57. Lancet 11 includes slotted hub 12 and sharp tip 13. *Id.* at 4:11–15. Protective cap 31

includes cylindrical member 32 with two open cavities. *Id.* at 4:27–29. Non-releasing cavity 34 at one end of protective cap 31 receives and envelops sharp tip 13 of lancet 11 after use. *Id.* at 4:29–33. Protective cap 31 also includes releasing cavity 37 for receiving and protectively-enclosing sharp tip 13 prior to use. *Id.* at 4:48–51. Breakaway contact points 38 adjacent releasing cavity 37 enable removal of protective cap 31 from lancet 11 by twisting. *Id.* at 4:51–56. Releasing cavity 37 serves as a releasable housing for lancet tip 13 until lancet 11 is ready to be used to prick skin. *Id.* at 4:56–59. Non-releasable cavity 34 serves as a non-releasable housing to envelop and protectively enclose a blood-contaminated sharp tip 13 after use. *Id.* at 4:59–63.

Figure 9 of Coe is reproduced below.

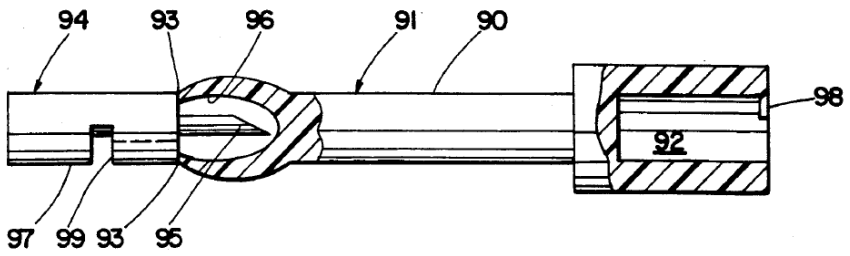


Fig. 9

Figure 9 of Coe depicts an embodiment of a lancet extractor that is integrally-molded to a lancet to protect the tip before use. *Id.* at 4:3–5. Extractor 91 includes handle portion 90 and extractor cavity 92 at one end. *Id.* at 5:22–24. The opposite end of extractor 91 has second cavity 96 covering sharp tip 95 of lancet 94. *Id.* at 5:25–28. Handle portion 90 attaches to lancet 97 at breakaway points 93, and twisting handle portion 09 breaks it away from lancet 97 to allow sharp tip 95 to be used. *Id.* at 5:28–33.

2. Summary of Sakata (Ex. 1107)

Sakata "relates to a lancet that is attached to a puncture device, for example, for use in collecting body fluids, such as blood, from tissues such as skin." Ex. 1107 ¶ 1. Sakata discloses a "lancet, consisting of a puncture needle, a holding portion for holding the puncture needle with the needle tip protruding therefrom, and a cap portion covering the above needle tip, and used by separating the above cap portion from the above holding portion." *Id.* ¶ 8.

Figure 2 of Sakata is reproduced below.

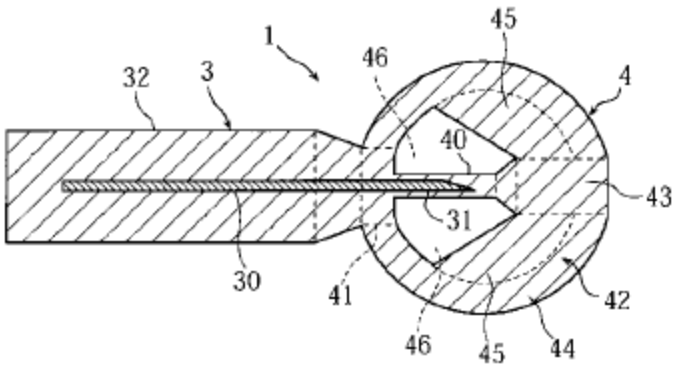
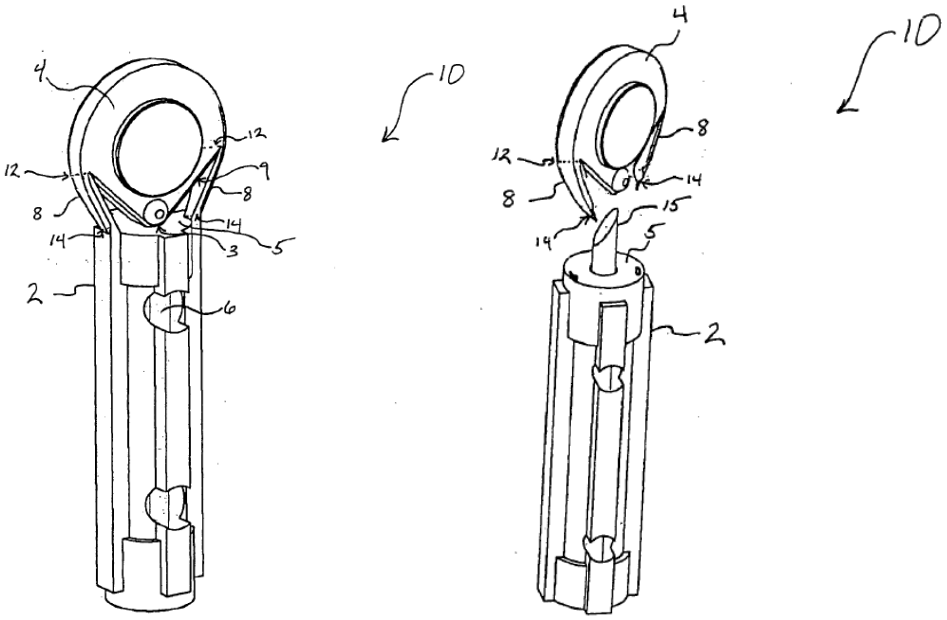


Figure 2 of Sakata is a cross-section view of a lancet according to one embodiment. *Id.* at 6. Lancet 1 includes lancet body 3 and integrally-molded cap portion 4 that can be separated from the body. *Id.* ¶ 14. Lancet body 3 includes puncture needle 30 and holding portion 32, from which needle tip 31 protrudes. *Id.* ¶ 15. Puncture needle 30 is insert-molded into lancet body 3 and cap portion 4. *Id.* Cap portion 4 includes small diameter covering portion 40, large diameter covering portion 41, and operating portion 42. *Id.* ¶ 16. Small diameter covering portion 40 protects needle tip 31 and maintains it in a sterile condition. *Id.* ¶ 17. Twisting operating portion 42 allows cap portion 4 to be separated from lancet body 3. *Id.* ¶ 20.

3. Summary of Starnes (Ex. 1108)

Starnes relates to "medical lancet devices that utilize protective caps for user safety and security." Ex. 1108 ¶ 3. Starnes states "that a need exists for an improved lancet design that overcomes . . . problems associated with visual and tactile misidentification of used lancets." *Id.* ¶ 11.

Figures 1 and 2 of Starnes are reproduced below.

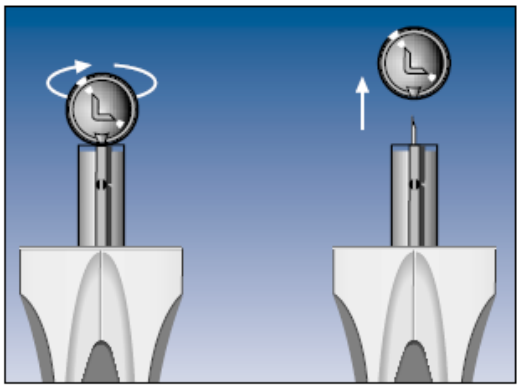


Figures 1 and 2 of Starnes show an improved lancet according one embodiment. *Id.* ¶¶ 15–16. Lancet unit 10 includes lancet body 2 and cap member 4, which is integrally joined to lancet body 2 by frangible junction 3. *Id.* ¶ 24. Exerting a twisting force by rotating cap member 4 relative to lancet body 2 causes frangible junction 3 to fracture so that cap member 4 can be removed to expose pointed end section 15. *Id.* ¶¶ 24, 30.

4. Summary of One Touch (Ex. 1110)

One Touch relates to blood glucose monitoring systems for diabetes management. Ex. 1110, 3.[9] One Touch discloses using a sterile lancet with a Penlet Plus Adjustable Blood Sampler (i.e., a lancet holder) to draw a blood sample for testing. *Id.* at 34–35.

A figure appearing on page 36 of One Touch is reproduced below.



The figure appearing on page 36 of One Touch shows a lancet being used with a Penlet Plus. *Id.* at 36. To draw a sample, a lancet is seated in the Penlet Plus, and a protective disk on the lancet is twisted to remove it and expose the needle tip. *Id.* at 35–36. After using the lancet, the needle tip may be pushed into the protective disk. *Id.* at 40.

5. Summary of Morita (Ex. 1109)

Morita "relates to a blood collection lancet, in particular, a lancet for pen-type finger-pricking devices." Ex. 1109 ¶ 1. Morita states that it seeks "to provide a lancet that is easy to use, does not cause hygienic problems such as infection during blood collection, and solves the problem of safety when disposing of the lancet after blood collection." *Id.* ¶ 12.

[9] We refer to the page numbers added by Petitioner at the lower right corner of Exhibit 1110.

Figure 3 of Morita is reproduced below.

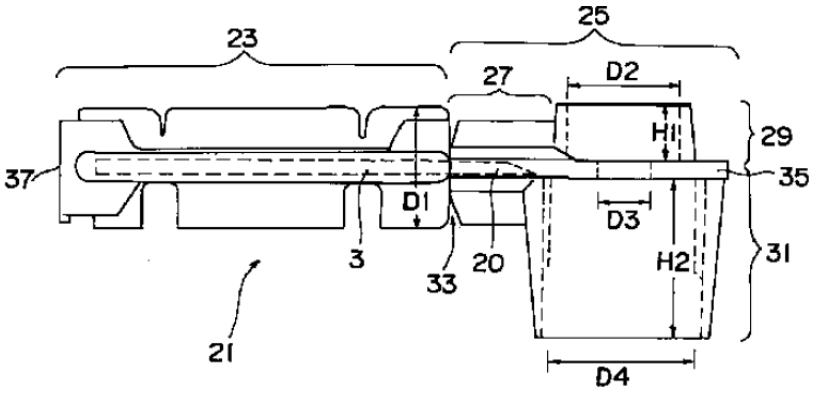


Figure 3 of Morita is a schematic side view of a lancet according to one embodiment. *Id.* ¶ 29. Lancet 21 includes lancet body 23 with protruding needle 20. *Id.* Protective platform 25 includes needle tip protection part 27 with a space for protruding needle 20, platform part 29, and end cap connection part 31. *Id.* Lancet body 23 and protective platform 25 are separated by rotating in opposite directions and pulling apart to expose needle 20 for use. *Id.* ¶ 33. After use, the end of lancet body 23 with protruding needle 20 is inserted into platform part 29 to be discarded. *Id.* ¶ 35.

B. Discretionary Denial Under 35 U.S.C. § 314(a)

The Petition, as filed, sought review of claims 1, 4, and 9–15 of the '635 patent. Pet. 4. The '712 Petition, as filed, sought review of claims 1–3, 5–8, 14, and 16–18 of the '635 patent. Because Petitioner has concurrently filed multiple petitions challenging claims of the same patent, we first consider whether we should exercise discretion to deny the second petition. *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 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 (Nov. 2019) ("CTPG")[10] states that "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). As noted above, Petitioner addressed the need for two petitions in its Ranking, including a request that we consider the Petition in this proceeding second to the '712 Petition. Ranking 1. Patent Owner argues that "[n]o exceptional circumstances exist to warrant the rare granting of two petitions on the same patent." Ranking Response 1.

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

To show that a second petition is warranted, Petitioner first argues that "the two petitions challenge different sets of claims" and "rely on distinct primary references." Ranking 2. According to Petitioner, the Petition "challenges claims requiring an 'open loop' feature," whereas the '712 Petition "does not." *Id.* The "open-loop" limitation to which Petitioner refers recites "the gripping handle portion comprises at least one open loop." Ranking 2; Ex. 1001, 8:48–49, 8:64–9:7, 10:13–14.

Petitioner's argument neglects the significant overlap in the claims challenged and issues presented between the two petitions. Independent claims 1 and 14 were challenged by Petitioner in both petitions. Moreover, claims 1 and 14 challenged in the Petition do not recite "an 'open loop' feature." Petitioner asserted four grounds of unpatentability directed to claims 1 and 14 in the '712 Petition and, in this proceeding, directs two additional grounds of unpatentability to claim 1 and three additional grounds of unpatentability to claim 14. We recognize that certain claims challenged in the Petition include the "open-loop" feature and depend from claim 1 or claim 14. Nevertheless, Petitioner does not suggest in its Ranking that a total of seven grounds across two petitions challenging claim 14, for example, is required. Nor does the mere fact that claims 4, 9–13, and 15 were not challenged in the '712 Petition show that a second petition was required. We find Petitioner's assertion that the two petitions challenge "different sets of claims" and that some of the claims challenged in the Petition include the "open-loop" feature insufficient to show that two petitions were required under the circumstances presented.

Petitioner further argues that "[c]hallenging the open-loop claims thus requires using different primary references and different obvious

combinations, and fitting all of this in one petition was not feasible." Ranking 2. Petitioner provides no additional explanation or support to show why "different primary references" were required or why presenting its arguments in a single petition "was not feasible." *See id.* While we understand Petitioner to suggest that the primary references relied on in the Petition were necessary to address the "open loop" feature, Petitioner relies in the Petition on those same references to challenge claims 1 and 14, which do not recite the "open loop" feature and were challenged in the '712 Petition based on other primary references. Thus, missing from Petitioner's argument is any assertion for why the primary references relied upon in the '712 Petition were required over the primary references asserted in this proceeding.

With regard to the feasibility of a single petition, Patent Owner shows that "[t]here is nothing unusual in the complexity of the '635 [p]atent's claims or the technology of the challenged patent and art that would distinguish it from many cases where one petition is sufficient." *See* Ranking Response 3. Patent Owner further shows that the claims are "not lengthy" and "are directed to a protective sterility cap for a lancet, which is not in a technology area with a fast-changing, complex landscape." *Id.*[11]

[11] Patent Owner also argues, and we agree, that neither of the circumstances identified by the CTPG as examples of situations where a second petition may be warranted are present in this proceeding. *See* Ranking Response 2, 4 (stating Patent Owner had only asserted 5 claims in district court when the petitions were filed and that "there is no dispute over the priority date"); CTPG 59 (stating more than one petition may be necessary "for example, when the patent owner has asserted a large number of claims in litigation or when there is a dispute about priority date requiring arguments under multiple prior art references").

Nor is it apparent from the relatively brief discussions of the "open-loop" limitation in the Petition why Petitioner's contentions could not have been included in a single petition. *See*, *e.g.*, Pet. 31–32.

In light of the technology at issue and the limited scope of the "open-loop" limitation, merely asserting without any further explanation that "different primary references and different obvious combinations" were required is insufficient to show that a second petition challenging claims of the same patent is warranted. Petitioner's conclusory assertion that a single petition was "not feasible" is likewise insufficient to show a second petition is required. As noted above, the CTPG explains that "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. Petitioner directs us to no reasoned argument to show that this proceeding lies outside "the vast majority of cases" or that two petitions were required, particularly in light of the brevity of the claims and the complexity of the technology at issue.

Second, Petitioner argues that had it not filed a second petition, it "would have risked surrendering its right to ever challenge the '635 patent's open-loop claims in an IPR proceeding." Ranking 2–3. Petitioner maintains that if it later filed a petition challenging the "open-loop claims," "even if not barred under 35 U.S.C. 315(e)," any subsequent petition "might still be denied due to non-merits-based (e.g., discretionary) reasons." *Id.* at 3. In response, Patent Owner argues that it does not assert Petitioner "infringes any of the open-loop claims in the parallel district court case," and that it is "unclear" how Petitioner "would be surrendering its rights if it did not challenge the open loop claims now." Ranking Response 5.

If we were to adopt Petitioner's logic, we would be obligated to simply presume a second petition challenging different or additional claims of the same patent is always warranted because there might be some reason why, in the future, a petition filed by the same petitioner could be discretionarily denied. We decline to adopt such an approach because it is neither reasonable nor consistent with the CTPG. *See* CTPG 59–60.

IV. CONCLUSION

We have reviewed the Petition and the '712 Petition and determine that, on the record presented 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 of the '635 patent. *See generally* Ranking. Accordingly, in light of our determination to institute *inter partes* review of the '635 patent on the claims challenged in the '712 Petition in IPR2023-00712, we exercise discretion under 35 U.S.C. § 314(a) to deny institution of the Petition in this proceeding.

IV. ORDER

Upon consideration of the record before us, it is:

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

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