UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner.

IPR2020-00126
IPR2020-00128
IPR2020-00129
IPR2020-00132
IPR2020-00134
IPR2020-00135
IPR2020-00137

PETITIONERS' SUR-SUR-REPLY TO PATENT OWNER'S SUR-REPLY ADDRESSING CONCEPTION AND REDUCTION TO PRACTICE

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I. INTRODUCTION

Teleflex asks the Board to conclude that VSI reduced its GuideLiner RX inventions to practice before Itou, based on conclusory, uncorroborated statements and a record devoid of meaningful documents. Even if the VSI documents are exactly what the inventors say they are, the record cannot support the inventors' sweeping assertions that they assembled and tested RX prototypes before September 23, 2005. Teleflex cannot carry its burden.

II. TELEFLEX MUST PROVE PRIOR INVENTION.

Teleflex misstates its burden—if the Board is uncertain about the CRTP evidence, then Teleflex has not satisfied its burden. Teleflex bears "the burden of going forward with evidence…and presenting persuasive argument based on" that evidence. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015). It must "establish[] that its claimed invention is entitled to an earlier priority date than an asserted prior art reference." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1376 (Fed. Cir. 2016). Prior invention is "effectively an affirmative defense." *Id.* Teleflex must prove that VSI invented before Itou, not Medtronic prove that VSI did not. *Apator Miitors ApS v. Kamstrup A/S*, 887 F.3d 1293, 1297 (Fed. Cir. 2018). The fact that Medtronic must prove unpatentability does not change that.

III. CONCEPTION

"Reduction to practice follows conception." *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996); *see REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954, 958 (Fed. Cir. 2016) (patentee "must either prove (1) a conception and reduction to practice…or (2) a conception…combined with diligence.").[1]

Teleflex appears to abandon its original conception documents and identifies later documents instead. Under Teleflex's new theory, *one* document supports conception of a complete invention: Ex-2022, dated August 1, 2005. Teleflex's other conception documents are either unwitnessed inventor documents (thus cannot corroborate), or component-part drawings that cannot show conception of every limitation of any claimed invention. Reply, 3-7; *Apple v. Yu*, IPR2019-01258, 2021 WL 41670, at *19 (PTAB Jan. 5, 2021) ("We disagree with Patent Owners' contention that the [document] does not need corroboration because it is a physical exhibit. [It] is a document that has been authenticated only by the testimony of the inventors. Thus, this document is one of the inventors' own statements and documents that depends solely on the inventor himself and, therefore, requires corroboration.").

[1] CRTP Response, 20 (acknowledging that cases "recite conception as an element of proof [for] actual reduction to practice").

The sole non-inventor document supporting conception of a complete invention—Ex-2022—undermines Teleflex's reduction-to-practice timeline. At best, Teleflex shows conception in August 2005, a mere month before Itou and *after* VSI's purported prototype work in April and July. Teleflex does not connect Ex-2022 to any *subsequent prototype*. Teleflex has shifted from arguing early 2005 conception with April/July 2005 reduction to practice to August 2005 conception with no subsequent reduction to practice. But reduction to practice necessarily *follows* conception.

IV. REDUCTION TO PRACTICE

Reduction to practice requires *constructing* an embodiment of the invention and *demonstrating* that the invention would work for its intended purpose. Reply, 7-8. The Board does not have evidence sufficient to conclude that VSI built, much less tested, RX prototypes before Itou.

A. Teleflex cannot prove that VSI assembled RX prototypes before Itou.

Teleflex failed to adduce evidence sufficient to prove RX assembly before Itou. Even if the component parts are exactly what Root says they are—two halves of an RX prototype—Teleflex offers only uncorroborated inventor say-so to prove successful assembly.

Only inventors discuss assembling the "April" and "July" components (Ex-2089 with Ex-2113 and Ex-2092 with Ex-2114). No non-inventor discusses

assembling these prototypes. Erb does not discuss these prototypes or component parts in his declaration. Ex-2122. And he could not discuss an assembled "July" prototype in any detail, even when *coached*. Ex-1756, 93:14-95:12 (discussing only Ex-2114).

No document corroborates assembly. Zalesky testified that though it does not "make a lot of sense" that VSI did not assemble prototypes, *it did not*—the record contains no assembly documents. Zalesky was unequivocal:

> 2113, 2092, and 2114, would it be reasonable for VSI to not assemble those parts together?
> A. I agree that doesn't make a lot of sense, but I can certainly conceive of using those parts for other purposes, for other potential designs, through other exploratory concepts.
> I just don't have any evidence that indicates how they were used or that they were assembled into any prototype.

Ex-2237, 208:10-25. Just before this exchange, counsel asked whether it would "be reasonable to order specialized parts…and not attach them," and Zalesky responded, "I said too many times that there simply is no evidence of an actual assembled prototype." *Id.*, 205:9-21.

The component-part drawings do not require pairing/assembly as the inventors discuss. The counterbore at the proximal end of the distal tubular portions (Ex-2089, Ex-2092) does not require attachment to the hypotube portions

(Ex-2113, Ex-2114). The counterbore would have enabled attachment to a variety of parts, including a *proximal tubular portion*, instead of an RX pushrod. Ex-1755 ¶¶95, 103, 179. Indeed, OTW guide catheters may be manufactured by fusing distal and proximal tubular portions, "to enable different mechanical properties at one end versus the other." Ex-2237, 49:19-51:18.[2]

Indeed, other documents show that VSI had *trouble* assembling an RX prototype and likely did not figure it out in the tight window between receiving RX parts and Itou. Assembly "took substantial engineering and testing." Ex-1770, 15; Reply, 22-27 (citing VSI documents showing RX did not leave proof-of-concept phase in 2005-2006 and that VSI did not have a working prototype as late as 2008). Teleflex does not explain these documents in its sur-reply. Moreover, Teleflex cannot explain why laboratory notebooks—including GuideLiner lead

[2] Teleflex hand-waves the similarity between OTW concept drawings and the "RX" distal portions, suggesting that the "chronology" does not work. But the record is littered with evidence that VSI was prototyping and testing OTW throughout 2005-2006. Reply, 9-10; Ex-2118 ¶19. The late-2005 OTW concept drawing is *consistent with*—not contrary to—OTW prototype work before then. Experimentation using different materials/dimensions goes hand-in-hand with proof-of-concept work. Ex-2237, 173:20-174:12, 181:6-19.

engineer Kauphusman's notebooks—logging VSI's engineering activities in 2005-2006 say nothing about assembling RX prototypes. Reply, 8-11. Teleflex asks the Board to believe that VSI accomplished successful assembly at an undisclosed time between arrival of component parts in summer 2005 and September 23, 2005, when documents suggest otherwise. Indeed, assembly was no easy task, requiring trial-and-error and comparing strength, flexibility, and breaking points for numerous options. Ex-1755 ¶73.

Without evidence to corroborate assembly, Teleflex tries to argue that Zalesky *concedes* assembly. Sur-reply, 8. Zalesky testifies to exactly the opposite. Based on years of experience with large and small companies, Zalesky opined that VSI would at least have assembly instructions if it assembled prototypes. Ex-1755 ¶¶66-74, 143-45; Ex-2237, 68:23-69:11, 134:8-138:3. Zalesky does not ask for too much: he delineates between early proof-of-concept documents and the more onerous regulatory phase. Ex-2337, 63:23-64:9, 66:1-9 (reduction to practice and "regulatory requirements" "are two very different issues"). Yet no document shows whether/when/how VSI assembled RX prototypes.

B. VSI needed to test RX prototypes, and Teleflex does not show that it did.

Even if VSI constructed an RX prototype, VSI needed to demonstrate that it would work for its intended purpose. Teleflex—for the first time in its sur-reply—contends that VSI did not need to test prototypes. But Teleflex's new argument

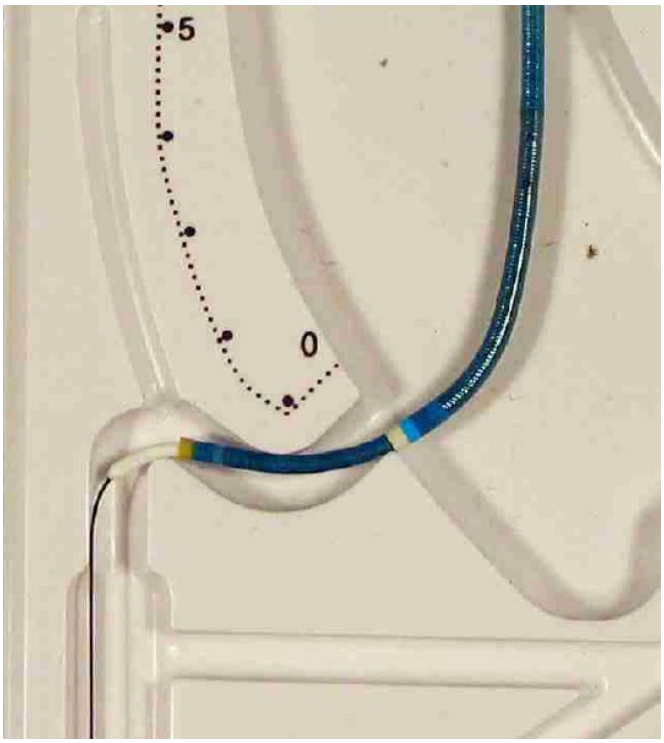
departs from its previous position,[3] expert and inventor testimony, and applicable law.

1. VSI needed to conduct particular testing to demonstrate that RX would work for its intended purpose.

The parties agree on the RX intended purpose: to increase backup support for accessing and crossing tough occlusions. Sur-reply, 9. According to the experts (Zalesky *and* Keith), to test whether the RX would increase backup support for accessing and crossing tough occlusions, VSI needed to set up a benchtop model simulating challenging anatomy (curvature, restrictions simulating lesions) and run the prototype through to test whether it would navigate the anatomy, access and cross simulated lesions, and stay in one piece through retrieval. Ex-1764, 64:2-67:12 (confirming that the *proper* simulation can test backup support, whether the tip deforms under pressure, kinking, and stent hang-up); Ex-1755 ¶¶233-37; Ex-2237, 28:18-29:9, 37:23-38:21. Only then would VSI have demonstrated that the prototype would work for its intended purpose.

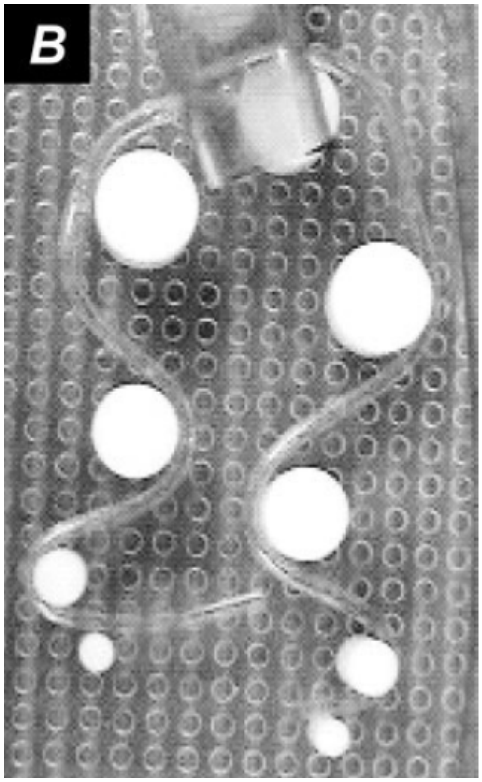
Teleflex offers no evidence that VSI performed this testing. The only benchtop model Teleflex alleges VSI even owned was, according to Zalesky, "very simple." Ex-2237, 135:5-23.

[3] CRTP Response, 25 ("Catheter inventions are routinely determined to work using benchtop models.").

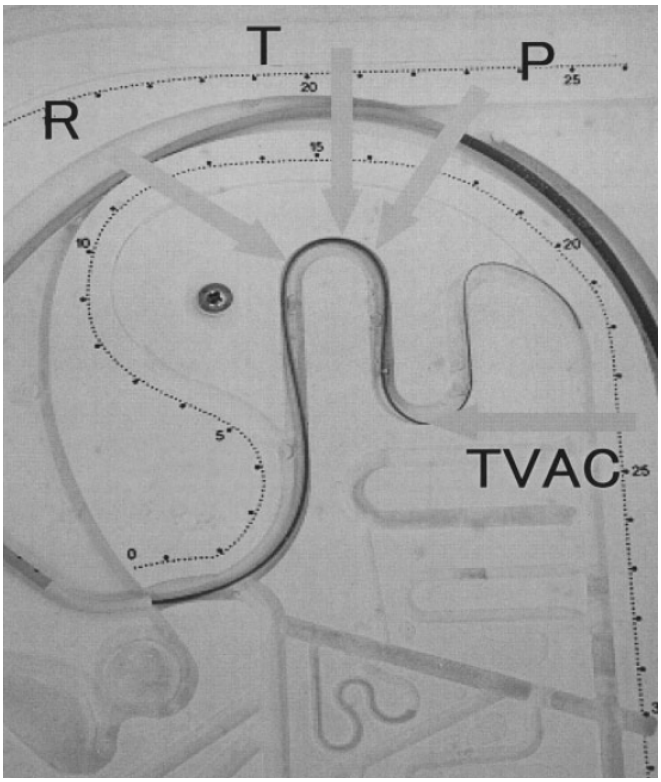


Ex-2129, 10 (showing OTW prototype)

Compare VSI's model with those designed to simulate challenging anatomy and tough occlusions:



Ex-1010, Fig. 1B
(demonstrating increased backup support)



Ex-1055, Fig. 2
(demonstrating improved crossing ability)

2. Reduction to practice requires *demonstrating* that the invention would work for its intended purpose, and demonstrating requires *testing* for all but the most primitive inventions.

Without exception, reduction to practice requires demonstrating that the invention would work for its intended purpose. Only primitive inventions demonstrate that workability upon construction and use, without testing. "[S]ome inventions are so simple and their purpose and efficacy so obvious that their complete construction is sufficient to demonstrate workability." *Mahurkar*, 79 F.3d at 1578. Traced to its origin, "so simple" refers to rudimentary 19th-century inventions, including "a clip made in one piece instead of two." *Mason v. Hepburn*,

13 App. D.C. 86, 87 (D.C. Cir. 1898). Even there, the inventors *constructed* and *demonstrated* to reduce to practice. Demonstrating that the inventions would work for their intended purposes did not require testing because the simple inventions worked upon complete construction and use. *Id.* at 90-91 (attaching "perfect construction" of clip to firearm magazine demonstrated that the clip was "capable of producing the result sought to be accomplished—namely, that of closing the magazine and clipping it to the barrel"). Even there, construction alone was not enough.

Demonstrating that an invention would work for its intended purpose requires testing in all but simple cases. "Reduction to practice occurs when the workability of an invention can be demonstrated….And this requires testing the invention." *E. Rotorcraft Corp. v. United States*, 384 F.2d 429, 431 (Ct. Cl. 1967). "Complex inventions…require laboratory tests that accurately duplicate actual working conditions in practical use." *Scott v. Finney*, 34 F.3d 1058, 1062 (Fed. Cir. 1994). Catheters, in particular, require testing. *Mahurkar*, 79 F.3d at 1578; *Bos. Sci. Corp. v. Johnson & Johnson*, 481 F. Supp. 2d 1018, 1024 (N.D. Cal. 2007) (reduction to practice after patentee "submitted documentation of the successful test results of a catheter embodying the…invention"). Teleflex conceded as much in its opening brief. CRTP Response, 24-25.

Teleflex cites neither case law[4] nor evidence to support its new "no testing" argument. It conflates obviousness with reduction to practice. Arguments regarding what would have been obvious to a POSITA do not relieve VSI of its obligation to demonstrate that the invention would work for its intended purpose. *Inferring* cannot replace *demonstrating*. Teleflex cannot repurpose Medtronic's invalidity expert by misapplying his testimony, and its own witnesses undermine its "no testing" theory. Keith did not offer a "no testing" opinion. Ex-1764, 49:8-14. And Root testified that VSI needed to test the prototype to confirm that it would work for its intended purpose. Ex-1762, 99:25-102:3.

[4] Teleflex cites a non-precedential Board decision and a CCPA opinion. Sur-reply, 9. Neither provides guidance regarding testing to reduce to practice. In *Pfizer v. Genentech*, patent owner offered "a detailed account of the construction *and testing*" of antibodies. IPR2017-01488, Paper 87 at 21 (PTAB Nov. 29, 2018) (emphasis added). The Board determined that patent owner did not need to show that it performed certain other tests because the claims did not require that particular characteristic. *Id.* at 23-24. The dispute concerned testing and the *scope of intended purpose*. *Stempel* had nothing to do with reduction-to-practice testing—it concerned antedating a species reference. 241 F.2d 755, 759 (C.C.P.A. 1957).

3. The Board cannot evaluate whether Teleflex's testing "evidence" proves that VSI demonstrated that RX would work for its intended purpose.

The Board cannot determine that VSI demonstrated that an RX prototype would work for its intended purpose based on Teleflex's conclusory, uncorroborated evidence. The Board judges "[t]he adequacy of a reduction to practice…by what one of ordinary skill in the art would conclude from the results of the tests." *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002). The Board considers "whether the testing in fact demonstrated a solution to the problem intended to be solved by the invention." *Scott*, 34 F.3d at 1063.

Teleflex offers no testing evidence that the Board can evaluate. The inventors offer conclusory say-so.[5] Regardless, no one corroborates them. No

[5] Root offers conclusory statements that VSI's undated testing in non-descript benchtop models "was sufficient" and showed that the "prototypes worked." Ex-2118 ¶¶18, 35; Ex-1762, 105:18-106:13 (testifying only "[w]e would test it in different anatomies and different angles and different vessels" and [w]e tested it in different take-offs and different simulated anatomy in the different benchtop models"), 100:18-22 (conceding "you could define [benchtop model] a lot of ways").

non-inventor discusses testing the April or July prototypes with any specificity. Erb offers no testimony regarding testing these prototypes, and he conceded that he "was not personally involved in" purported tests "involving the delivery of stents and balloons." Ex-2122 ¶¶11-12; Ex-1756, 71:11-73:20. Erb does not explain how any testing demonstrated that the prototype would work for its intended purpose—Erb does not even *mention* the intended purpose. Ex-2122 ¶13 (stating only "we knew from our early testing of prototypes of the device that it would work"). Schmalz offers less than Erb. She has no first-hand knowledge of any testing, cannot judge whether a prototype would work for its intended purpose, and can only *assume* that engineers outside her department tested prototypes based on an unreliable, unauthenticated document that she did not prepare. Reply, 21; Paper 106/109/110/111/112 (Motion to Exclude Ex-2024). *Cf. Scott*, 34 F.3d at 1063 (wherein the Court had the opportunity to evaluate a video showing specific testing of a prosthetic implant). The Board needs *something* to judge.

* * *

Under the rule of reason, VSI did not reduce to practice before Itou. Indeed, Zalesky, a POSITA with a long history of developing interventional cardiology catheters, opined that it is not reasonable to conclude that VSI assembled and tested RX prototypes before Itou. Ex-2237, 41:13-42:17, 228:10-229:8, 232:2-16 (testifying that it is not reasonable to infer that the record supports assembly and

testing, as "[i]t's inconceivable that you wouldn't retain at least that small minimal subset [of documents] I mentioned").

V. DILIGENCE

Teleflex offers no rebuttal to Medtronic's diligence arguments.

VI. TELEFLEX CANNOT PROVE PRIOR INVENTION OF EVERY CLAIMED INVENTION.

Teleflex needed to adduce evidence sufficient to prove prior invention *of each claimed invention*. Reply, 2-3. Teleflex did not argue prior invention claim-by-claim in its opening brief. And its attempt to backdoor claim-by-claim proof by arguing against Zalesky's claim-by-claim *rebuttal* falls short and cannot satisfy its burden of production.

Zalesky understood the claims (though he did not provide claim construction opinions) and considered Root's arguments related to the April and July RX prototypes in light of the claims. Ex-2237, 200:2-12, 217:23-218:6. Zalesky shows how Root's arguments do not satisfy every limitation of every claimed invention. Ex-1755, App'xs A-E. Teleflex is missing evidence that the RX prototypes met at least these claim limitations:

Claims	**Missing Limitation**
'032, claims 1, 11 '380, claims 1, 12	"substantially rigid portion…[operably] connected to…flexible tip portion"
'032, claims 3, 4	"the tubular structure further comprises structure defining a proximal side opening" or "the side

’380, claims 3, 4, 36	opening is incorporated with the proximal end of the reinforced portion”
’776, claims 25, 52, 53 ’760, claims 25, 48, 51, 53	“a segment defining a [side opening/partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure]”
’776, claim 48	“the partially cylindrical opening and the tubular structure comprise a reinforced portion of the guide extension catheter”
’032, claims 6, 11 ’380, claims 1, 12, 25 ’776, claim 44 ’379, claims 25, 38 ’760, claims 35, 51	“reinforced portion proximal to the flexible distal tip portion” (and similar limitations) July prototype does not satisfy. Neither prototype satisfies when claiming flexible tip segment distinct from reinforced segment.
’032, claims 8, 17 ’380, claims 8, 18, 32 ’776, claims 30, 53 ’379, claim 34 ’760, claims 25, 48, 51, 53	“the cross-sectional inner diameter of the coaxial lumen of the [flexible distal portion/tubular structure] is not more than one French smaller than the cross-sectional inner diameter of the guide catheter” (and similar limitations) July prototype does not satisfy.

Even if the Board considers Root’s claim-by-claim arguments, they cannot fill these holes in Teleflex’s record.

VII. INCORPORATION BY REFERENCE

Teleflex concedes that it incorporated Root’s claim-by-claim arguments by reference, in violation of 37 C.F.R. § 42.6(a)(3). Instead of disputing its rule violation, Teleflex argues that its case is unique and *warrants* its departure from the Board’s rules because it has “invested substantial resources” in its case and

wants a decision on the merits. Sur-reply, 18-20. Teleflex pleads for exceptional treatment.

Teleflex never objected to the Board's order for consolidated CRTP briefing. It never suggested that it would not be able to meet its burden in light of applicable briefing rules and orders. Indeed, the consolidated briefing schedule "made sense" to Teleflex, and they chose to prioritize arguments untethered to "the specific language of a particular claim in a particular patent." Ex-2233, 6:3-14. Teleflex chose the issues it briefed. It chose to ignore its claim-by-claim burden.

This is not the first time that Teleflex has argued for special treatment when presenting its CRTP case. It argued against equal briefing between the parties, wanting more words than Medtronic. Ex-1099/1299/1699, 8:5-10:19. It tried to obtain an advisory opinion from the Board regarding Medtronic's incorporation by reference argument. Ex-2233, 10:9-23. In filing its sur-replies, it departed from the Board's order consolidating briefing and submitted five different briefs in an attempt to salvage its claim-by-claim arguments. The Board should disregard the additional briefing as a violation of the word count.

Teleflex's suggestion that Medtronic's "procedural" argument is inappropriate or late is meritless. Medtronic raised the issue in its reply to Teleflex's infringing CRTP brief. Medtronic had no obligation to raise the issue related to Teleflex's burden any earlier.

VIII. CONCLUSION

Teleflex cannot prove invention before Itou.

Dated: February 23, 2021

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

I certify that Petitioners' Sur-Sur-Reply to Patent Owner's Sur-Reply Addressing Conception and Reduction to Practice consists of 2,800 words not including its incorporation by reference section, and 268 words in its incorporation by reference section, in 14-point Times New Roman font, as calculated by the word count feature of Microsoft Office 2016, in compliance with 37 C.F.R. § 42.24(a)(i). This word count is inclusive of all text and footnotes but does not include the table of contents, table of authorities, mandatory notices under § 42.8, certificate of service, certificate of word count, or appendix of exhibits or claim listing.

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CERTIFICATE OF SERVICE

I certify that on February 23, 2021, a copy of PETITIONERS' SUR-SUR-REPLY TO PATENT OWNER'S SUR-REPLY ADDRESSING CONCEPTION AND REDUCTION TO PRACTICE was served in its entirety by electronic mail on Patent Owner's counsel at the following addresses indicated in Patent Owner's Mandatory Notices:

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