
**UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

In Re: U.S. Patent 10,531,883 : Attorney Docket No. 088594.0102

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Assignee: RapidPulse, Inc.

Title: Aspiration Thrombectomy System and Methods for Thrombus Removal
with Aspiration Catheter

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Submitted Electronically

**SUPPLEMENTAL DECLARATION OF BRIAN BROWN FOR INTER
PARTES REVIEW OF U.S. PATENT NO. 10,531,883**

RapidPulse, Inc.
Exhibit 2005
Penumbra v. RapidPulse
IPR2024-01261
Ex. 2005-001

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List of Exhibits

1001	U.S. Patent No. 10,531,883 (“the ’883 Patent”)
1002	U.S. Provisional Application No. 62/701,086
1003	U.S. Provisional Application No. 62/750,011
1004	Prosecution File History of the ’883 Patent
1005	Expert Declaration of Brian Brown
1006	CV of Brian Brown
1007	U.S. Patent No. 11,096,712 (“Teigen”)
1008	U.S. Provisional Application No. 62/702,804 (the “’804 Provisional”)
1009	U.S. Provisional Application No. 62/778,708 (the “’708 Provisional”)
1010	International Application No. WO 2014/151209 A1 (“Grey”)
1011	U.S. Patent No. 3,955,574 (“Rubenstein”)
1012	U.S. Patent Publication No. 2017/0238953 A1 (“Yang”)
1013	U.S. Patent Publication No. 2012/0138833 A1 (“Matteo”)
1014	PATRICIA E. THORPE & FRANCISCO J. OSSE, <i>Endovenous Management of Iliocaval Occlusion</i> , in THE VEIN BOOK, 2007 MECHANICAL THROMBECTOMY
1015	Dave Fornell, <i>Catheter-Based Clot Busting Therapies</i> , DIAGNOSTIC AND INTERVENTIONAL CARDIOLOGY (Feb. 4, 2013), https://www.dicardiology.com/article/catheter-based-clot-busting-therapies
1016	International Application No. WO 2018/019829 A1 (“Brady”)
1017	Gilles Rioufol et al., <i>Large Tube Section Is the Key to Successful Coronary Thrombus Aspiration: Findings of a Standardized Bench Test</i> , 67 CATHETERIZATION & CARDIOVASCULAR INTERVENTIONS 254-

	257 (Dec. 5, 2005), https://onlinelibrary.wiley.com/doi/10.1002/ccd.20471
1018	Michael Haude, <i>Mechanical Thrombectomy Catheter Systems</i> , 2 INTERVENTIONAL CARDIOLOGY 58-60 (2007), https://www.icrjournal.com/articles/thrombectomy-catheter-systems
1019	U.S. Patent No. 3,086,528 (“Eichelman”)
1020	U.S. Patent No. 3,659,605 (“Sielaff”)
1021	U.S. Patent No. 3,042,042 (“Blanck”)
1022	Scott Simon, et al., <i>Exploring the Efficacy of Cyclic vs. Static Aspiration in a Cerebral Thrombectomy Model: An Initial Proof of Concept Study</i> , 6 J. NEUROINTERVENT. SURG. 677 (Dec. 14, 2014)
1023	Expert Declaration of Ian Ross, MD
1024	CV of Ian Ross, MD
1025	U.S. Patent Publication No. 2010/0204672 A1 (“Lockhart”)
1026	U.S. Patent No. 4,634,435 (“Ingraham”)
1027	Stephan A Munich, et al., Overview of Mechanical Thrombectomy Techniques, 85 NEUROSURGERY S60-S67 (June 14, 2019) https://academic.oup.com/neurosurgery/article/85/suppl_1/S60/5512732
1028	06/10/2021 Response to Office Action during prosecution of U.S. Patent No. 11,096,712 (“Teigen”)
1029	06/23/2021 Notice of Allowance during prosecution of U.S. Patent No. 11,096,712 (“Teigen”)
1030	Supplemental Expert Declaration of Brian Brown
1031	Finol Deposition Transcript
1032	Chen Deposition Transcript

I, Brian Brown, declare as follows:

1. My name is Brian Brown. I am an engineering consultant in the area of medical device design, development, manufacturing and intellectual property. My CV is available as Exhibit 1006.

2. I have been retained by Baker Botts L.L.P. (“Counsel”) on behalf of Penumbra Inc. (“Petitioner” or “Penumbra”) to offer opinions in connection with *Inter Partes* review of U.S. Patent No. 10,531,883 (“the ’883 Patent”). I have previously submitted a declaration (“Original Declaration” or Ex. 1005) in connection with Penumbra’s petition on August 26, 2021. I incorporate that information into this declaration, relating to Petitioner’s Reply to Patent Owner’s Response.

3. I have considered information from various sources in forming my opinions. I have reviewed and considered each of the exhibits listed above in the Table of Exhibits and papers filed in this proceeding in forming my opinions.

I. Level of Skill of One of Ordinary Skill in the Art

4. I have proposed a level of skill for a person of ordinary skill in the art (“POSA”) in my Original Declaration. Ex. 1005, ¶ 48. I understand that the Board adopted my proposed definition of a POSA in the Institution Decision (“ID”). ID at 9.

5. Patent Owner and its expert, Dr. Finol, disagree and argue that “individuals with a B.S. degree and undefined engineering discipline or an interventional neurosurgeon with no engineering training would lack the necessary background in mechanical engineering and fluid mechanics” to be a person of ordinary skill in the art for the ’883 Patent. Patent Owner Response (“PO Response”) at 6; Ex. 2014, ¶¶ 42-44. Patent Owner instead takes the position that a person of ordinary skill in the art must have “a B.S. in mechanical engineering with at least three years of experience in designing systems for minimally invasive intravascular procedures.” Ex. 2014, ¶¶ 42-44.

6. I disagree that mechanical engineering is the sole degree that would qualify as a person of ordinary skill in the art. I also understand that both of Patent Owner’s experts, Dr. Ender Finol and Dr. Michael Chen each contradicted with Patent Owner’s definition of a POSA during their cross-examination. For example, Dr. Finol was asked “if you were to replace mechanical engineering with a biomedical engineering graduate, would such a person, in your view, be your person of ordinary skill in the art of the Deville 883 patent?”, to which Dr. Finol answered “yes, I would feel comfortable replacing the word mechanical with biomedical.” Ex. 1031 at 45:21-46:7. Similarly, Dr. Chen was asked “do you qualify as a person of

ordinary skill in the art under the definition by Dr. Finol?”, Dr. Chen answered, “I think nobody would qualify under the definition.”¹ Ex. 1032 at 74:5-11.

7. In my opinion, Patent Owner’s definition of a person of ordinary skill in the art places more stringent requirements on both the academic background and industrial experience of a person of ordinary skill in the art than would be required for the ’883 Patent. However, I believe that the obviousness of the ’883 Patent claims would not change based on Patent Owner’s definition of a person of ordinary skill in the art. In my opinion, the claims of the ’883 are obvious to a person of ordinary skill in the art under both Patent Owner’s definition and the definition I provided.

II. Claim Construction

8. For purposes of this *Inter Partes* Review I have considered the claim language, specification, and relevant portions of the prosecution history, to determine the meaning of the claim language as it would have been understood by a person of ordinary skill in the art at the time of the invention.

9. I have afforded all claim terms not identified below their plain and ordinary meaning as understood by a POSA at the time of the invention.

¹ I understand that Dr. Chen subsequently confirmed that he does not qualify as a person of ordinary skill in the art. Ex. 1032 at 75:19-22.

A. “the change in the level of vacuum at the distal end is greater than approximately [15, 20, or 25] inHg and no greater than approximately [50, 30, or 20] ms”

10. The phrase “the change in the level of vacuum at the distal end is greater than approximately [15, 20, or 25] inHg and no greater than approximately [50, 30, or 20] ms” appears in Claims 10-12 with slightly different numerical values and is addressed together here as one term. As I explained in my Original Declaration, a POSA would have understood the term “the change in the level of vacuum at the distal end is greater than approximately [15, 20, or 25] inHg and no greater than approximately [50, 30, or 20] ms” to mean the change in the level of vacuum from low to high or from high to low at the distal end is greater than approximately [15, 20, or 25] inHg and the time for that change is no greater than approximately [50, 30, or 20] ms. Ex. 1005, ¶¶ 80-82. I understand that Patent Owner’s expert Dr. Finol agrees that my “clarification is accurate.” Ex. 2014, ¶ 40.

B. “forward flow”

11. The claims of the ’883 Patent require the system to “prevent forward flow of the distal portion out from the distal end during each cycle.” I understand that the Board construed “forward flow” to mean an amount of liquid in the lumen that exits the distal end in the distal direction that is greater than 6 microliters. *See* ID at 26.

12. I also understand that Patent Owner and Dr. Finol declined to specifically construe “forward flow,” but proposed various interpretations of what preventing forward flow “means” in arguing the priority date of the ’883 Patent. *See, e.g.*, PO Response at 30; Ex. 2014, ¶ 89. (“a POSITA would have understood that “prevent forward flow of the distal portion out from the distal end during each cycle” means “controlling the distal movement of the fluid column such that the distal portion of the fluid column is prevented from fully exiting the distal end of the catheter during each cycle.”) I further understand that Dr. Finol provided various inconsistent positions relating to “forward flow” in his testimony during cross-examination. Ex. 1031 at 104:13-118:22. I agree with the Board’s construction, and I disagree with Patent Owner and its expert’s confusing interpretations.

13. In my opinion, a person of ordinary skill in the art would understand “forward flow” as “an amount of liquid in the lumen that exits the distal end in the distal direction that is greater than 6 microliters.”

14. This construction is consistent with the specification of the ’883 Patent, which is explicit regarding the meaning of the term “forward flow,” using such clear and unambiguous language such as “define” and “defined.” Ex. 1001 at 36:18-22. For example, the ’883 Patent specification states: “The term ‘forward flow’ is used herein to *define* an amount of liquid in the lumen **662** that exits the distal end **664** in

a distal direction. Forward flow is *defined as greater than 6 microliters of fluid.*”

Ex. 1001 at 36:18-22.²

15. This construction is also consistent with the use of “forward flow” in the context of Claims 1, 15, and 18 where it is recited. For example, Claim 1 recites “the controller configured to... *prevent forward flow of the distal portion* out from the distal end during each cycle.” Ex. 1001 at 55:31-35. I understand that in claim construction, there is a presumption that claim terms should be construed to have meaning. Applying this construction in place of the claim language, a person of ordinary skill in the art would understand this limitation as “*prevent an amount of liquid greater than 6 microliters of the distal portion* out from the distal end during each cycle,” which ensures that all of the claim terms are given meaning.

16. Patent Owner and Dr. Finol argue that “there is ‘no forward flow’ until the full extent of the distal portion of the fluid column has exited the distal end of the catheter.” PO Response at 31; Ex. 2014, ¶ 86.

17. I disagree with Patent Owner’s position because it abandons the clear numerical delineation of forward flow “defined as greater than 6 microliters of fluid” and resorts to an ambiguous concept of a “full extent of the distal portion,” which

² Unless otherwise noted, I have supplied any emphasis added throughout my declaration.

precludes any clear means of determining no-forward flow. I also disagree with Patent Owner’s expansion of the scope of “the full extent of the distal portion” such that the distal portions of the liquid column can apparently be an arbitrarily selected amount (e.g., less than 20 microliters or less than 5 microliters), an arbitrarily selected length (e.g., a few mm or cm), or any portion of the column approximated by a statistical flow analysis. PO Response at 31; Ex. 2014, ¶ 87. A person of ordinary skill in the art would recognize that under Patent Owner’s proposed construction, “the full extent of the distal portion” could be an endless number of arbitrarily selected metrics.³

³ Dr. Finol’s note of a miscalculation of column length in the ’883 Patent is irrelevant because Dr. Finol has also proposed no less than three distinct column lengths (1 mm, 2 mm, 2.3 mm) that might equate to 6 microliters, which further reinforces the uncertainty of the column length metric. Ex. 2014 at fn. 1; Ex. 1031 at 101:3-7. Additionally, the ’883 specification clearly defines forward flow in terms of volume instead of catheter length, which only “approximately” corresponds with the inventors’ express definition. Ex. 1001 at 36:18-23 (“Forward flow is *defined* as greater than *6 microliters* of fluid (*approximately 1 mm* of catheter length...)”).

18. In my opinion, Patent Owner's construction effectively eliminates the entire concept of preventing forward flow, because it would permit any arbitrarily selected amount of fluid to leave the catheter, displacing the thrombus to be recovered a corresponding distance away from the catheter tip into the patient's narrow vasculature, resulting in the very risk of distal migration that the '883 Patent intends to avoid. Ex. 1001 at 2:65-3:4 ("Forward flow...can and does remove thrombi off of the distal end and risk sending thrombi further distally in the vasculature"), 37:45-54 ("The prior art repetitively opens and closes that vacuum valve. Thus, an amount of liquid ejects in a periodic manner out of the distal opening in those devices. This forward flow phenomena is undesirable in the area of thrombus removal because, when liquid is allowed to eject from the distal end and the physician is causing the distal end to approach the thrombus, the liquid could or will move the thrombus further distally").

19. Patent Owner's requirement for "fully exiting" is also unsupported by the specification of the '883 Patent, which does not discuss or even mention anything "fully exiting" the distal end of the catheter. PO Response at 30; Ex. 2014, ¶ 86. Patent Owner relies only on Dr. Finol's declaration to support its "fully exiting" requirement, but Dr. Finol does not point to anything in the '883 Patent to support this concept of "fully exiting." PO Response at 30, 33-35, 39; Ex. 2014, ¶¶ 86, 89-91, 93-94.

20. I also understand that on cross-examination, Dr. Finol abandoned the construction proposed in his declaration and adopted a different position that contradicts Patent Owner's construction and also makes the no-forward-flow requirement meaningless. Ex. 1031 at 110:2-6, 112:13-17. According to Dr. Finol, "the definition of forward flow is such that *the entire distal portion of the column of fluid* exits the distal end of the catheter, [and] *is then drawn back into the catheter* during each cycle. That's how you would prevent forward flow." Ex. 1031 at 110:2-6. Dr. Finol also gave the example that "If 20 microliters leave the distal end of the catheter during one phase of the cycle, as long as those 20 microliters are withdrawn back into the catheter during another phase of the cycle before the cycle ends, then we have essentially prevented forward flow." Ex. 1031 at 112:13-17.

21. Basically, Dr. Finol's testimony went completely outside of his declaration and the Patent Owner Response, and took the position that "prevent forward flow" allows any amount of liquid to flow forward out of the distal end so long as, at some later point in the cycle, that same amount of liquid is eventually drawn back into the catheter. In my opinion, this is both illogical and directly counter to stated purpose of this technology, preventing the thrombus from flowing downstream. Ex. 1001 at 2:65-3:4, 37:45-54. Permitting an unrestricted amount of fluid to flow distally out of the distal end would make no sense to a person of skill

in the art, regardless of whether the fluid is ultimately retrieved, because the thrombus would have long since escaped the catheter tip.

III. Priority Date

22. The '883 Patent was filed on July 18, 2019, and claims priority to two prior provisional applications, U.S. Provisional Application No. 62/701,086 filed on July 20, 2018 (the "'086 Provisional" or "Deville-Prov1") and U.S. Provisional Application No. 62/750,011 filed on October 24, 2018 (the "'011 Provisional" or "Deville-Prov2"). Ex. 1001 at 1; Ex. 1002 ('086 Provisional); Ex. 1003 ('011 Provisional). U.S. Patent No. 11,096,712 ("Teigen '712") was issued on August 24, 2021, from U.S. Patent Application No. 16/988,556 filed on August 7, 2020. Teigen claims priority to U.S. Provisional Application No. 62/702,804 (the "'804 Provisional" or "Teigen-Prov1") filed on July 24, 2018, and U.S. Provisional Application No. 62/778,708 (the "'708 Provisional" or "Teigen-Prov2") filed on December 12, 2018. Ex. 1007 (Teigen '712) at 1; *see also* Ex. 1008 ('804 Provisional); Ex. 1009 ('708 Provisional).

23. I understand that Patent Owner and Dr. Finol argue that the Teigen '712 Patent is not prior art because (1) the claims of the '883 Patent are entitled to priority benefit of Deville-Prov2 and (2) the Teigen '712 Patent is not entitled to priority

benefit of Teigen-Prov1.⁴ PO Response at 7-43; Ex. 2014, ¶¶ 45-142. Patent Owner is wrong on both accounts.

24. As I explain below, it is my opinion that Teigen '712 is prior art to the '883 Patent. Teigen '712 is entitled to priority benefit of both Teigen-Prov1 and Teigen-Prov2, whereas the '883 Patent is not entitled to priority benefit of any provisional application. Because the '883 Patent is not entitled to any priority benefit, Teigen '712 is prior art so long as it is entitled to priority benefit of either of its provisional applications, both predating the priority of the '883 Patent. Alternately, Teigen '712 is prior art at least for its priority to Teigen-Prov1 because Patent Owner does not even assert that the '883 Patent is entitled to priority benefit of Deville-Prov1. PO Response at 41, Ex. 2014, ¶ 74.

A. The '883 Patent is not Entitled to Priority Benefit of Either Deville Provisional Application

25. It is my opinion that the claims of the '883 Patent are not entitled to a priority date earlier than July 18, 2019, at least because neither provisional application describes or enables the claim limitation of “prevent forward flow of the

⁴ To the extent that Patent Owner produces evidence to support that the '883 Patent is entitled to an earlier priority date, I reserve the right to submit rebuttal opinions not limited to the opinions provided in this declaration.

distal portion out from the distal end during each cycle,” as required by each of the Challenged Claims under any construction.

26. The '883 Patent describes a mode of operation that expressly relies on forward distal flow (referred to herein as “forward-flow” operation) to create forward distal movement of the clot that is stuck. Ex. 1001 at 30:16-57. Deville-Prov2 also describes the forward-flow mode of operation that expressly relies on forward distal movement of fluid in the same manner, using language matching the forward-flow mode of operation described in the '883 Patent. Ex. 1003, ¶ 0126 (mirroring Ex. 1001 at 30:16-57).

27. The '883 Patent explicitly sets apart the description of the forward-flow mode of operation from subsequent modes of operation that prevent forward flow (“no-forward-flow” operation). The '883 Patent states after describing the forward-flow mode of operation depicted in Deville-Prov2: “The flow of fluid forward in this exemplary embodiment is intentional, which is in contrast to other exemplary embodiments herein where substantially no forward flow occurs.” Ex. 1001 at 30:58-60. The '883 Patent then explicitly turns to the description of the no-forward-flow mode of operation: “Turning now to embodiments... without the forward flow.” Ex. 1001 at 35:19-20. Hence, by the express admission of the '883 Patent, Deville-Prov2 does not describe or enable the claim limitation of “prevent forward flow of the distal portion out from the distal end during each cycle.”

28. Patent Owner and Dr. Finol attempted to rely on their ambiguous and illogical construction of “prevent forward flow” to overcome the express description of forward flow in Deville-Prov2. PO Response at 30-35; Ex. 2014, ¶¶ 86-93. As I explained above, Patent Owner’s construction is not supported by the specification and claims of the ’883 Patent, and contradicts the understanding of a person of skill in the art. In any case, Deville-Prov2 fails to provide priority support to the Challenged Claims of the ’883 Patent even under Patent Owner’s incorrect construction.

29. Patent Owner and Dr. Finol argue that Deville-Prov2 describes “a minimal amount of momentum transfer from the fluid column to the stuck clot to unstick the clot sufficiently,” which purportedly teaches no-forward-flow. PO Response at 33-34; Ex. 2014, ¶¶ 89-91. However, Patent Owner and Dr. Finol do not point to anything in Deville-Prov2 that limits the amount of exit flow to below 6 microliters, as the ’883 specification defines forward flow, or even to “20 microliters,” an upper limit of distal portion that Patent Owner identified. PO Response at 31; Ex. 2014, ¶ 87.⁵ In fact, the examples quoted by Patent Owner

⁵ As another example of Patent Owner’s mischaracterizations of Deville-Prov2, Patent Owner and Dr. Finol argue that Deville-Prov2 teaches the internal diameter (“I.D.”) values required by Claim 13 of the ’883 Patent (between 0.038" and

permit exiting distal flow of up to “approximately 1.0 ml,” i.e., 1000 microliters, which far exceeds any amount that Patent Owner could reasonably characterize as the full distal portion. PO Response at 33-34; Ex. 2014, ¶¶ 89-91. Dr. Finol confirmed in his testimony that Deville-Prov2 permits “approximately 1,000” microliters to leave distal end of the catheter. Ex. 1031 at 109:12-13. A person of skill in the art would not allow for forward flow of up to 1000 microliters, and would not consider doing so as “prevent[ing] forward flow” by any standard.⁶ In my opinion, nothing in the disclosure of Deville-Prov2 would direct a person of skill in the art to limit the exiting distal flow to “no greater than 6 microliters of fluid,” as required by the claims.

0.106"). PO Response at 37; Ex. 2014, ¶¶ 127, 131. For Claim 13, Patent Owner cites only to Deville-Prov2’s disclosed I.D. values “of approximately 0.055 to 0.095 inches.” PO Response at 37; Ex. 2014, ¶¶ 127, 131. Patent Owner does not point to any other disclosure in Deville-Prov2 supporting the significantly different diameters in Claim 13, which were clearly not contemplated in Deville-Prov2.

⁶ Patent Owner and Dr. Finol also do not point to anything in Deville-Prov2 that discloses withdrawing the liquid that exited the distal end during the first half of the cycle, as Dr. Finol testified regarding “prevent forward flow.” Ex. 1031 at 110:2-6.

30. Patent Owner and Dr. Finol further argue that “if a POSITA would have understood Grey as teaching ‘preventing forward flow’ based on the mere mention of ‘non-zero suction’ to ‘prevent distal migration’..., a POSITA would have been able to visualize ‘preventing forward flow’ given the more definitive teachings of Deville-Prov2.” PO Response at 35; Ex. 2014, ¶¶ 89-91. But there is no valid comparison here because Patent Owner points to nothing in Deville-Prov2 that teaches “non-zero suction” or “prevent distal migration.” Moreover, I understand that obviousness is a separate analysis from written description, and that a description that renders an invention obvious does not necessarily satisfy the written description requirement. Patent Owner and Dr. Finol’s argument premised on “if a POSITA would have understood Grey as teaching “preventing forward flow...” improperly conflates the obviousness analysis with the written description requirement.

B. The Teigen ’712 Patent is Entitled to Priority Benefit of Both Teigen-Prov1 and Teigen-Prov2

31. I understand that for patentability analysis for post-AIA patents, a provisional application that a prior art post-AIA patent claims a right of priority to only needs to describe the subject matter of the prior art post-AIA patent. As I have previously explained, it is my opinion that the subject matter relied upon in the Teigen ’712 Patent for this IPR was fully described in its provisional applications—Teigen-Prov1 and Teigen-Prov2. Ex. 1005, ¶¶ 86, 104-248, 290-312.

32. I understand that Patent Owner and Dr. Finol suggest that the requirement for pre-AIA prior art patents that a provisional application support at least one claim of the non-provisional patent should also be applied to post-AIA patents such as the Teigen '712 Patent. As shown below, at least claim 1 of Teigen '712 is supported and enabled by both provisional applications.

a) Teigen-Prov1 Fully Supports and Enables at Least Claim 1 of Teigen

(1) Teigen claim 1 preamble: “A clot removal system, comprising:”

[1a]: “a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a distal portion”

[1b]: “a controllable vacuum valve”

[1c]: “a vacuum source fluidically connected to the vacuum valve”

[1d]: “a controllable vent valve having a vent liquid input”

[1e]: “a vent fluid source containing a vent liquid and fluidically connected to the vent valve to retain the vent liquid at the vent fluid input”

[1f]: “a manifold connected to the catheter, to the vacuum valve, and to the vent valve, the manifold fluidically connecting the proximal portion of the liquid column in the lumen: to the vacuum source through the vacuum valve; and to the vent fluid source through the vent valve”

As explained in my Original Declaration, preamble and elements [1a]-[1f] of claim 1 of Teigen '712 are full described and enabled by Teigen-Prov1. Ex. 1005, ¶¶ 87-93. Patent Owner and Dr. Finol do not dispute my analysis of these elements. PO Response at 42-45; Ex. 2014, ¶¶ 52-73.

(2) Teigen claim limitation [1g]: “a controller connected to the vacuum valve and the vent valve and configured to selectively open and close the vacuum valve and the vent valve such that: responsive to opening the vacuum valve, the vacuum source is fluidically connected to the liquid column in the lumen; and responsive to opening the vent valve, the vent fluid source is fluidically connected to the liquid column in the lumen, the controller configured to cyclically open and close the vacuum valve and the vent valve to: change a level of negative and positive pressure at the distal end; and control flow of the distal portion in and out from the distal end during each cycle”

33. As explained in my Original Declaration, Teigen-Prov1 also provides adequate written description and enablement support for claim limitation [1g]. Ex. 1005, ¶¶ 94-95.⁷

⁷ I note that this limitation was inadvertently mislabeled as [1e] in my Original Declaration. It is clear from the list of claim limitations that it should instead be 1[g], as the Board has correctly recognized. ID at 16.

34. Patent Owner and Dr. Finol argue that Teigen-Prov1 does not support limitation [1g] of Claim 1 of the Teigen '712 Patent. PO Response at 42-45; Ex. 2014, ¶¶ 52-73. I disagree.

35. Teigen-Prov1 discloses a controller “configured to” (i.e., “capable of”) (1) change a level of negative and positive pressure at the distal end, and (2) control flow of the distal portion in and out from the distal end during each cycle.⁸ Teigen-Prov1 discloses this *capability* based on the design of the clot removal device, which is consistent with the descriptions in Teigen-Prov1 and the prosecution history of the Teigen '712 Patent. For example, Teigen-Prov1 discloses a clot removal device including, among other things, a vacuum source and a vent fluid source, both fluidically connected through controllable valves to a catheter having a lumen filled with a liquid column, such that a controller, through opening and closing valves, is capable of changing a level of negative and positive pressure at the distal end and

⁸ I understand that during the prosecution of the Teigen '712 Patent, the Examiner interpreted “configured to” to mean “capable of” in considering the prior art. Ex. 2012 at 126 (“The venting mechanism of Garrison is not *capable of* providing a positive pressure to the distal end of the catheter such that fluid flows out of the distal end of the catheter.”). It is my opinion that is how a POSA would have understood the term “configured to.”

controlling flow of the distal portion in and out from the distal end during each cycle. Ex. 1008, ¶¶ 0063-0064. Indeed, the Teigen '712 Patent Examiner explained that the claims of the '712 Patent were novel over the prior art based on the same structures disclosed in Teigen-Prov1 that allow “chang[ing] a level of negative a[nd] positive pressure at the distal end of the catheter and to control flow of a liquid column in the catheter in and out of the distal end during each cycle.” Ex. 1029 at 6.

36. Additionally, Teigen-Prov1 demonstrates the capability of generating positive pressure and distal flow. For example, paragraph [0063] of Teigen-Prov1 states “A saline injection valve 296 controls the flow of saline, typically through an injection tube 295, to inject pulse into the clot flow path when necessary to break up clot.” Ex. 2008, ¶ 0063. A POSA would have understood that in order for the injected saline to “break up clot,” there is necessarily some positive pressure to cause a distal force against the clot.

37. A person of skill in the art would understand that Teigen-Prov2 further clarifies and supports the disclosure of the controller capability already described in Teigen-Prov1. Indeed, Teigen-Prov2 clarifies that the same clot removal device can “create a positive pressure.” Ex. 1009, ¶ 0067. Patent Owner and Dr. Finol does not dispute that Teigen-Prov2 expressly teaches in certain embodiments “a positive pressure at the distal end of the catheter” and “flow of a liquid column in the catheter out of the distal end.” PO Response at 26; Ex. 2014, ¶¶ 72-73.

38. Patent Owner and Dr. Finol make several disjointed arguments regarding Teigen-Prov1, each of which I disagree with. First, while Patent Owner appears to agree that “configured to” merely requires “ability to control,” (PO Response at 14; Ex. 2014, ¶ 56), Patent Owner argues that the “configured to” language “limits this claim to requiring ‘positive pressure’ at the distal end” and “a flow in the distal direction that exits the catheter.” PO Response at 13; Ex. 2014, ¶ 56. Patent Owner’s construction is so narrow that it requires “control flow into the distal end of the catheter during one phase of the cycle and out from the distal end during another phase of the cycle during *each cycle* when such flow occurs,” clearly contradicting the embodiment examples in the specification. PO Response at 14; Ex. 2014, ¶ 56. For example, Figure 20 of the Teigen ’712 Patent shows a range of pressure within the catheter including both positive *and* negative pressures. I understand that claims should generally not be construed such that it would exclude the preferred embodiment disclosed in the patent, as Patent Owner’s very narrow construction would do here.

39. Second, Patent Owner and Dr. Finol argue that “paragraph [0064] teaches that the saline “reduc[es] the vacuum, which necessarily means some level of vacuum remains in the catheter.” PO Response at 18; Ex. 2014, ¶ 62. But,

“reducing” vacuum does not preclude generating a “positive pressure.”⁹ Ex. 2008, ¶ 0064. Indeed, in a similar paragraph of Teigen-Prov2, it restates “reducing that vacuum with saline” as “an increase in pressure with fluid.” *Compare* Ex. 2008, ¶ 0064 *with* Ex. 2009, ¶ 0066. In my opinion, “reducing vacuum” and “increase in pressure” have the same meaning. Other POSITA’s use this language in this way as well. Ex. 1010 (Grey) at 6:3-4 (“a reduction in positive pressure is equivalent to an increase in negative pressure”).

40. Patent Owner and Dr. Finol further argue without support that the saline source of Teigen-Prov1 is at ambient pressure. PO Response at 19-20, 23; Ex. 2014 at 69. But, a “saline source” is often used at a positive pressure without requiring a pump, e.g., a saline source is commonly positioned in an elevated position to ensure flow of saline into the patient, as admitted by Dr. Finol. Ex. 1031, 77:5-24. Moreover, Patent Owner further concedes that “it is *possible* a combination of these factors could produce a positive pressure pulse in the catheter when the saline is at

⁹ Patent Owner and Dr. Finol also argue “[w]hen the vacuum is ‘partially reliev[ed]’ by the influx or bolus of saline, the catheter is still subject to vacuum and the pressure remains negative.” PO Response at 22; Ex. 2014 at ¶ 67. But “partially relieve the vacuum” corresponds to merely one mode of operation of the system, not the only mode of operation. Ex. 2008 at ¶ 0065.

ambient pressure.” PO Response at 19-20; Ex. 2014, ¶ 64. In any case, a person of skill in the art would have understood that Teigen-Prov1 at least discloses a clot removal system having a controller that is capable of changing a level of negative and positive pressure at the distal end. Moreover, Patent Owner’s argument that Teigen-Prov1 discloses no-positive pressure contradicts its own assertion that the Teigen ’712 Patent does not disclose no-forward flow. PO Preliminary Response (“POPR”) at 27-32; Ex. 2001, ¶¶ 52-62. Patent Owner cannot have it both ways: if Teigen-Prov1 teaches no-positive pressure at the distal end, the Teigen ’712 Patent, which incorporates Teigen-Prov1 by reference must also disclose no-forward flow.

41. Finally, Patent Owner’s argument that the Teigen ’712 Patent requires flow out of the distal end is based on an incorrect construction of that claim. The claim requires only that the “controller...**control flow**...in and out.” Ex. 1007 at Claim 1. However, “control flow...out” can be achieved by **preventing** flow out of the catheter. For instance, the Grey reference demonstrates that the term “control” can mean “having an influence or effect that is intended and/or predictable.” Ex. 1010 at 6:13-14, 8:2-8. Thus, a person of skill in the art would understand that prevention of flow out is more than sufficient to perform the claimed requirement to “control flow...out.”

42. Therefore, the Teigen '712 Patent is entitled to priority benefit of Teigen-Prov1 even under the analysis for pre-AIA patents proposed by Patent Owner.

b) Teigen-Prov2 Fully Supports and Enables at Least Claim 1 of Teigen

43. The Teigen '712 Patent is also entitled to priority benefit of Teigen-Prov2, even under Patent Owner's proposed analysis, at least because Claim 1 of the Teigen '712 Patent is fully described and enabled by Teigen-Prov2. As shown in detail below, Teigen-Prov2 provides support to preamble and elements [1a]-[1f] of claim 1 of Teigen '712 in the same or similar way to what is described and enabled by Teigen-Prov1, which Patent Owner and Dr. Finol do not dispute. PO Response at 42-45; Ex. 2014, ¶¶ 52-73. Moreover, Patent Owner and Dr. Finol concede that element 1[g] of the Teigen '712 Patent is supported by Teigen-Prov2. PO Response at 24-26; Ex. 2014, ¶ 73.

(1) Teigen claim 1 preamble: "A clot removal system, comprising:"

44. Teigen-Prov2 discloses a clot removal system. For example, under the sub-heading of "Field of the Invention," Teigen-Prov2 states that "the invention described herein relates to devices and methods for controlling clot removal from a patient's vasculature by aspiration thrombectomy," which a POSA would have understood as a clot removal system. Ex. 1009 at ¶002.

(2) Teigen claim limitation [1a]: “a catheter having a distal end and defining a lumen filled with a liquid column having a proximal portion and a distal portion”

45. Teigen-Prov2 discloses that “the present invention provides a vacuum aspiration control system for use with a vacuum source and an aspiration catheter” and a “connecting tube [] configured to connect the vacuum source to an aspiration lumen in the aspiration catheter.” Ex. 1009 at ¶0014. Teigen-Prov2 further discloses “engaging a distal end of an aspiration catheter against an occlusion in the blood vessel.” Ex. 1009 at ¶0020. A POSA would have readily recognized that the “aspiration lumen in the aspiration catheter” would be filled with a liquid column having a proximal portion and a distal portion, as recited in claim limitation [1a].

(3) Teigen claim limitation [1b]: “a controllable vacuum valve”

46. Teigen-Prov2 discloses that an “on-off valve sits between the juncture 292 and the vacuum console to cut off vacuum pressure when necessary,” and that “the system will initiate pulsated aspiration. When this happens, the system will modulate the valve to the pump,” “partially relieve the vacuum,” and “After a short period of time... reestablish the aspiration vacuum,” which a POSA would have understood as a controllable vacuum valve. Ex. 1009 at ¶¶0065-0067.

(4) Teigen claim limitation [1c]: “a vacuum source fluidically connected to the vacuum valve”

47. Teigen-Prov2 discloses that the clot removal system includes “a vacuum aspiration control system for use with a vacuum source and an aspiration catheter,” and that an “on-off valve sits between the juncture 292 and the vacuum console to cut off vacuum pressure when necessary.” *See, e.g.*, Ex. 1009 at ¶¶0014, 0065-0067. A POSA would have readily recognized that the vacuum console is fluidically connected to the on-off valve to control the vacuum pressure.

(5) Teigen claim limitation [1d]: “a controllable vent valve having a vent liquid input”

48. Teigen-Prov2 discloses that the clot removal system will open and close a “Fluid injection valve 296 [to] control[] the flow of fluid,” which a POSA would have understood as a controllable vent valve having a vent liquid input. Ex. 1009 at ¶¶0065-0067.

(6) Teigen claim limitation [1e]: “a vent fluid source containing a vent liquid and fluidically connected to the vent valve to retain the vent liquid at the vent fluid input”

49. Teigen-Prov2 discloses that the clot removal system includes a “fluid introduction unit 290,” and that “the system will modulate the valve to the pump and, at least partially, open the valve 296 to the fluid reservoir 290, pump 298, and pressure chamber 297” and “close or modulate valve 296 to reestablish the aspiration vacuum.” *See, e.g.*, Ex. 1009 at ¶¶0065-0067. A POSA would have readily

recognized that the fluid introduction unit 290 is fluidically connected to the vent valve.

(7) Teigen claim limitation [1f]: “a manifold connected to the catheter, to the vacuum valve, and to the vent valve, the manifold fluidically connecting the proximal portion of the liquid column in the lumen: to the vacuum source through the vacuum valve; and to the vent fluid source through the vent valve”

50. Teigen-Prov2 discloses “a manifold connected to the catheter, to the vacuum valve, and to the vent valve, the manifold fluidically connecting the proximal portion of the liquid column in the lumen: to the vacuum source through the vacuum valve; and to the vent fluid source through the vent valve.” For example, Teigen-Prov2 states that “[t]he system comprises a connecting tube, an on-off valve, a sensing unit, and a controller. The connecting tube is configured to connect the vacuum source to an aspiration lumen in the aspiration catheter.” Ex. 1009 at ¶0014. Teigen-Prov2 further discloses a system configuration that “pulsate[s] the aspiration pressure to reduce clogging and promote flow of the clot and thrombus through the aspiration catheter and connecting tubing,” as shown in Fig. 13 of Teigen-Prov2 below. Ex. 1009 at ¶0065.

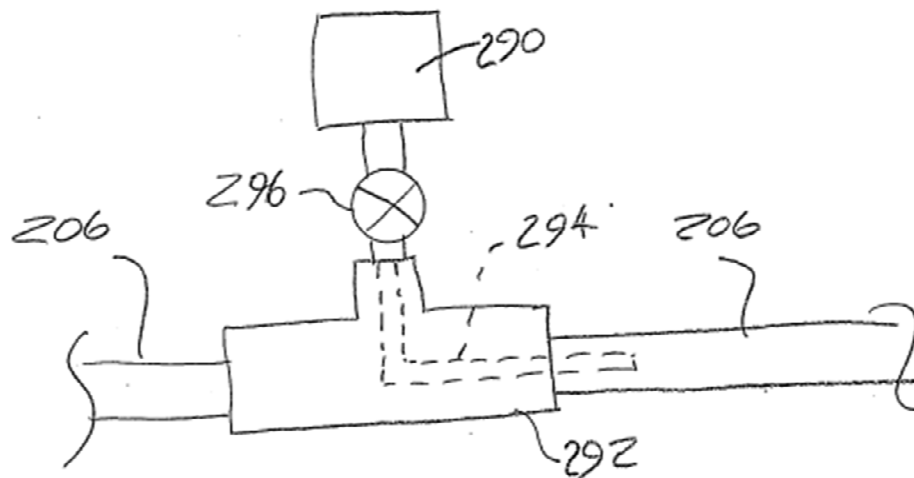


FIG-13

Ex. 1009 at Fig. 13. Here, the connection tubing 206 “connects a fluid introduction unit 290 to the aspiration catheter and the vacuum console.” Ex. 1009 at ¶0065. Accordingly, Teigen-Prov2 discloses “a manifold connected to the catheter, to the vacuum valve, and to the vent valve, the manifold fluidically connecting the proximal portion of the liquid column in the lumen: to the vacuum source through the vacuum valve; and to the vent fluid source through the vent valve.”

(8) Teigen claim limitation [1g]: “a controller connected to the vacuum valve and the vent valve and configured to selectively open and close the vacuum valve and the vent valve such that: responsive to opening the vacuum valve, the vacuum source is fluidically connected to the liquid column in the lumen; and responsive to opening the vent valve, the vent fluid source is fluidically connected to the liquid column in the lumen, the controller configured to cyclically open and close the vacuum valve and the vent valve to: change a level of negative and positive pressure at the

distal end; and control flow of the distal portion in and out from the distal end during each cycle”

51. Teigen-Prov2 discloses this claim limitation. For example, Teigen-Prov2 states that “the present invention provides a vacuum aspiration control system for use with a vacuum source and an aspiration catheter.” Ex. 1009 at ¶¶0014, 0047-0049 (disclosing a microprocessor controller 74 as an embodiment of the controller), ¶¶0059-0060 (disclosing controller 220 as another embodiment). “A vacuum is applied through an aspiration lumen of the aspiration catheter using a vacuum source coupled to a proximal end of the aspiration lumen by a connecting tube.” Ex. 1009 at ¶0022. “The controller is connected to receive the signal representative of flow through the connecting tube and to open and close the on-off valve in response to the signal.” Ex. 1009 at ¶0014. Teigen-Prov2 explains that during dynamic/pulsed aspiration, the on-off valves including the vacuum source valve and the pressure source valve are modulated by the controller by alternating between opening and closing the valves to “change a level of negative and positive pressure at the distal end; and control flow of the distal portion in and out from the distal end during each cycle.” Ex. 1009 at ¶¶0065-0067. Indeed, Dr. Finol concedes that “a POSITA would [] understand that the inventors [] had possession of the concept of using a ‘positive pressure,’ and thus [] had possession of the concept of ‘flow...out from the distal end’ of the catheter, as of the December 12, 2018 filing date of Teigen-Prov2.” Ex. 2014, ¶73.

52. Given the well-known components and detailed descriptions provided in Teigen-Prov2, a POSA would have understood that the inventors are in possession of the invention claimed in Claim 1 of Teigen '712 and it requires no undue experimentation to practice the claim. Therefore, it is my opinion that Teigen-Prov2 provides adequate written description and enablement support for Claim 1 of Teigen '712.

53. For at least the reasons explained above, the Teigen '712 Patent is prior art to The '883 Patent.

IV. Claims 1, 4, 5, and 13-17 are Obvious in View of Teigen '712 and Grey

54. I understand that Patent Owner and Dr. Finol do not contest that the combination of the Teigen '712 Patent and the Grey reference disclose the limitations of Claims 1, 4, 5, and 13-17. PO Response at 43-45; Ex. 2014, ¶¶ 144-153. Instead, Patent Owner argues against the motivation to combine the Teigen '712 Patent and Grey for these claims based largely on a misunderstanding of the requirements on the Teigen '712 Patent's disclosure. As explained in my Original Declaration, and as explained further here, a person of skill in the art would have been motivated to combine Teigen '712 and Grey to provide more efficient and effective cyclical aspiration of blood clots. Ex. 1005, ¶¶ 104-111.

55. Dr. Finol argues that Grey could not be combined with Teigen '712 because "Grey's system does not have a vacuum valve to cut-off the vacuum source

from the catheter such that vacuum is always applied throughout the procedure.” Ex. 2014, ¶ 151. But Grey’s disclosure does not prohibit the inclusion of a vacuum valve. A POSA would find it obvious to control the vacuum suction with the vacuum valve expressly disclosed in Teigen ’712 to modulate the dynamic aspiration. Requiring Grey to explicitly recite a vacuum valve misunderstands the combination of Teigen ’712 and Grey. Teigen ’712 already teaches the combination of vent and vacuum valves. Dr. Finol further misunderstands what Grey provides, among other things, is the motivation to prevent forward flow at the distal end by management of various parameters, such as aspiration fluid pressure and valve cycle times.

56. Patent Owner and Dr. Finol also repeat the argument that the operation of Teigen ’712 and Grey are “mutually exclusive” and that “[t]he principles of fluid dynamics prevent [] reconciliation” of “Grey’s teachings of ‘providing a non-zero suction force in the catheter at all times’ with Teigen ’712’s requirement of having a ‘positive pressure.’” Ex. 2014, ¶¶ 147, 152. This argument fails because it is grounded on the mischaracterization that Teigen ’712 requires flow out of the distal end. Notably, Patent Owner and Dr. Finol do not cite to anything in the specification of Teigen ’712 that requires a positive pressure or forward flow. In fact, Teigen ’712 clearly teaches that the pressure generated by introducing the fluid into the catheter can be “at a pressure between full vacuum and ambient pressure,” i.e., a non-positive pressure. Ex. 1007 at 15:37-39. Patent Owner even concedes that “Teigen-Provl

explicitly teaches there would be... no ‘flow out from the distal end’ of the catheter.”

PO Response at 22; Ex. 2014, ¶ 67.

57. Patent Owner and Dr. Finol also make several related arguments that all essentially rely on the underlying mischaracterization that closing the vacuum valve necessarily creates and results in forward flow. However, these arguments are inconsistent with the principles of fluid dynamics, and are contradicted by the disclosure of Teigen ’712 and its provisional applications, and by admissions from Dr. Finol and Patent Owner.

58. The assertion that closing the vacuum valve necessarily creates and results in forward flow is also inconsistent with Patent Owner’s and Dr. Finol’s position that Teigen-Prov1 can’t have forward flow when the vacuum valve is closed. For example, when Dr. Finol was asked “in Teigen’s system, [] when the vacuum valve is closed, is it possible for the liquid inside the catheter to still have a negative pressure?” he responded “Teigen is stating that the system is going to close the on/off valve to the pump and open the valve 296 to the saline injection unit 290. As a consequence of that operation then, there’s an influx of saline that will *partially relieve the vacuum*. So regardless of how Teigen thinks that his – he’s operating his system, the consequence of that on/off valve operation is a partial relief of vacuum.” Ex. 1031 at 93:20-94:9.

59. Dr. Finol also clarified that “since there’s a partial relief of vacuum, I interpret that as a POSITA -- and I imagine any other POSITA would understand in the same way -- that **the pressure inside the catheter remains negative, and therefore, there cannot be any flow coming out of the distal end.**” Ex. 1031 at 91:10-15.

60. Accordingly, Dr. Finol and Patent Owner admit that closing the vacuum valve does not necessarily lead to a positive pressure or forward flow. I agree with this because, particularly when the tip of the catheter is obstructed, the system becomes closed and thus, in the absence of an injection of sufficient vent fluid, there would continue to be negative pressure within the catheter, even after the vacuum valve is closed. As such, Teigen ’712 teaches an influx of saline to relieve that vacuum.

61. It also follows that a double-closed state does not inherently increase the risk of creating forward flow. Patent Owner and Dr. Finol appear to understand this concept as well: “Moreover, a POSITA also would understand that merely opening and closing the vacuum and pressure valves to deliver ‘saline pulsated aspiration’ as discussed in Teigen-Prov1 would not inherently produce a positive pressure pulse sufficient to overcome the mean arterial pressure necessary for ‘flow...out from the distal end of the catheter.’” PO Response at 18; Ex. 2014, ¶ 63.

62. Lastly, I disagree with Patent Owner's and Dr. Finol's various arguments regarding general factors that would motivate a person of skill in the art to combine Teigen '712 and Grey. As I explained in my Original Declaration and again here, a person of skill in the art would have been motivated to combine the teachings of Teigen and Grey because they address similar problems related to convention aspiration thrombectomy and share the common objective of improving aspiration efficiency. Ex. 1005, ¶¶ 104-111. Teigen and Grey both teach similar solutions involving a liquid source to temporarily vent/relieve vacuum within the catheter to create an accelerated suction force to efficiently remove blood clots from a patient's blood vessel into the device. Ex. 1005, ¶¶ 104-111. Teigen and Grey both describe issues with clogged catheters and the limitations of static aspiration technologies for controlled clot aspiration. Ex. 1005, ¶¶ 104-111; Ex. 1007 at 1:57-3:32, 14:61-15:33; Ex. 1008, ¶¶ 005, 009, 0063-0065; Ex. 1009, ¶¶ 006, 008, 0011, 0065-0067; Ex. 1010 at 1:7-2:3. Teigen and Grey both describe a similar approach of creating a dynamic aspiration force to more effectively clear clots from a clogged catheter. Ex. 1005, ¶¶ 104-111; Ex. 1007 at 2:24-3:48, 14:61-18:7; Ex. 1008, ¶¶ 006-0010, 0063-0065; Ex. 1009, ¶¶ 007-009, 0011, 0012, 0065-0067; Ex. 1010 at 2:24-3:24.

63. Combining the teachings of Teigen and Grey would have been well within the skill of a person of skill in the art because it is nothing more than

combining known vacuum aspiration technologies described in these references to perform their intended functions with described benefits and predictable results, such as improving Teigen '712's system using Gray's teachings regarding the design of aspiration profiles to minimize clot migration risks while improving clot clearance results. Ex. 1005 ¶¶ 104-111. Finally, a person of skill in the art would have had a reasonable expectation of success in combining the disclosures of Teigen and Grey because it would have been well within a person of skill in the art's level of skill to modify the logic of Teigen's controller to implement Grey's teachings, and/or to incorporate well-known mechanical components, if needed, to carry out the functionality described in Grey. Ex. 1005, ¶¶ 104-111.

V. Claims 2-3 and 6-9 are Obvious in View of Teigen '712 and Grey

64. Patent Owner and Dr. Finol argue against the obviousness of the “double-closed state” limitation recited in Claims 2-3 and 6-9 in view of Teigen '712 and Grey. Patent Owner's arguments are that (1) the “double-closed state” “have no support in either Teigen-Prov1 or Teigen-Prov2” and (2) the “double-closed state” is “inconsistent with Petitioner's arguments for combining Teigen '712 and Grey.” PO Response at 46-49; Ex. 2014, ¶¶ 154-161.¹⁰

¹⁰ I note that neither the PO Response nor Dr. Finol's supplemental declaration articulates any purported benefit achieved by the claimed “double-closed state,”

65. Regarding Patent Owner’s first argument, a person of skill in the art would have understood that Teigen ’712 discloses a double-closed state, which is also supported by both Teigen-Prov1 and Teigen-Prov2. Ex. 1005, ¶¶ 162-65; Ex. 1007 at 16:51-18:7, Ex. 1008, ¶¶ 0063, 0065, 0069; Ex. 1009, ¶¶ 0065, 0067, 0070. Teigen ’712 discloses a serial operation of the vacuum and vent valves; thus, it would be natural, preferable, and obvious to have a double closed state. Ex. 1007 at 17:5-7 (“[i]n other overlapping sequences, sometimes both valves are open and both valves are closed for at least short periods of time”). Teigen-Prov1 and Teigen-Prov2 similarly disclose that the vacuum valve and fluid injection valve can each be selectively opened or closed when necessary, e.g., to cut off the vacuum and injection of the fluid in the catheter. Ex. 1008, ¶¶ 0063, 0065, 0069; Ex. 1009, ¶¶ 0065, 0067, 0070. The Teigen provisional applications are consistent with the serial operation of the vacuum and vent valves disclosed in Teigen ’712.

66. For example, Teigen-Prov1 explains that “...the system will initiate pulsated aspiration. When this happens, the system will **close the on-off valve** to the pump and **open the valve 296** to the saline injection unit 290. An influx or bolus of

nor could there be since the “double-closed state” is merely a typical state during the serial operation of the valve system disclosed in Teigen ’712 and the Teigen provisional applications. PO Response at 46-57; Ex. 2014 at ¶¶ 154-161.

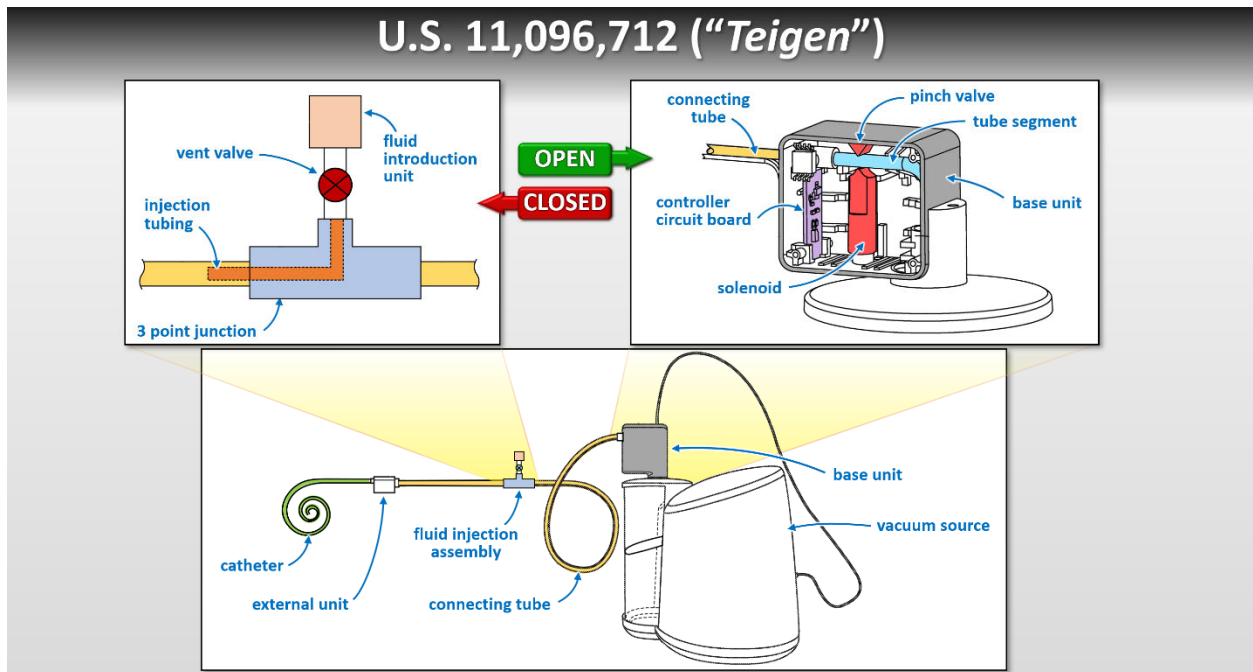
saline will partially relieve the vacuum. After a short period of time the system will **close valve 296** and *reopen the on-off valve* to reestablish the aspiration vacuum.”

Ex. 1008, ¶ 0065.

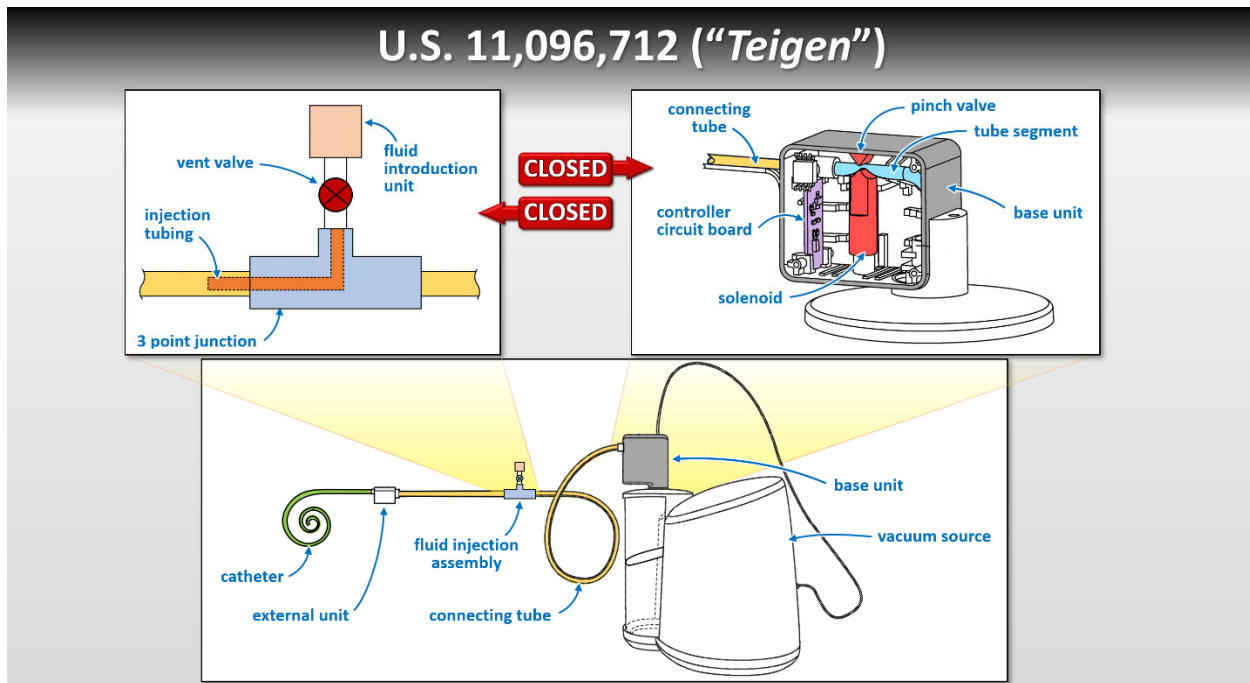
67. This understanding of sequential operation of valve operation is further reinforced by Teigen-Prov1’s statement that the cycle entails “applying a vacuum, *followed by reducing that vacuum with saline...*” and that “[w]hile aspiration is cycled off, saline injection is cycled on *until* aspiration is turned back on.” Ex. 1008, ¶¶ 0064, 0069. A person of skill in the art would recognize that Teigen-Prov1 and Teigen-Prov2 both contemplate that the steps of (1) closing the vacuum valve, (2) opening the saline valve, (3) closing the saline valve, and (4) opening the vacuum valve could be performed in the sequence in which they are disclosed either serially or in parallel, and that neither provisional application teach against either mode of operation.

68. In my opinion, it is far more typical and reliable to conduct serial operations in medical devices. For example, an automated valve typically includes position sensors to tell whether the valve is in an open or closed state. It is far more reliable for a controller to initiate a valve operation and verify the completion of the valve operation before proceeding with the other valve operation. Parallel operations also tend to compound operation errors of the parallel steps, reducing system reliability.

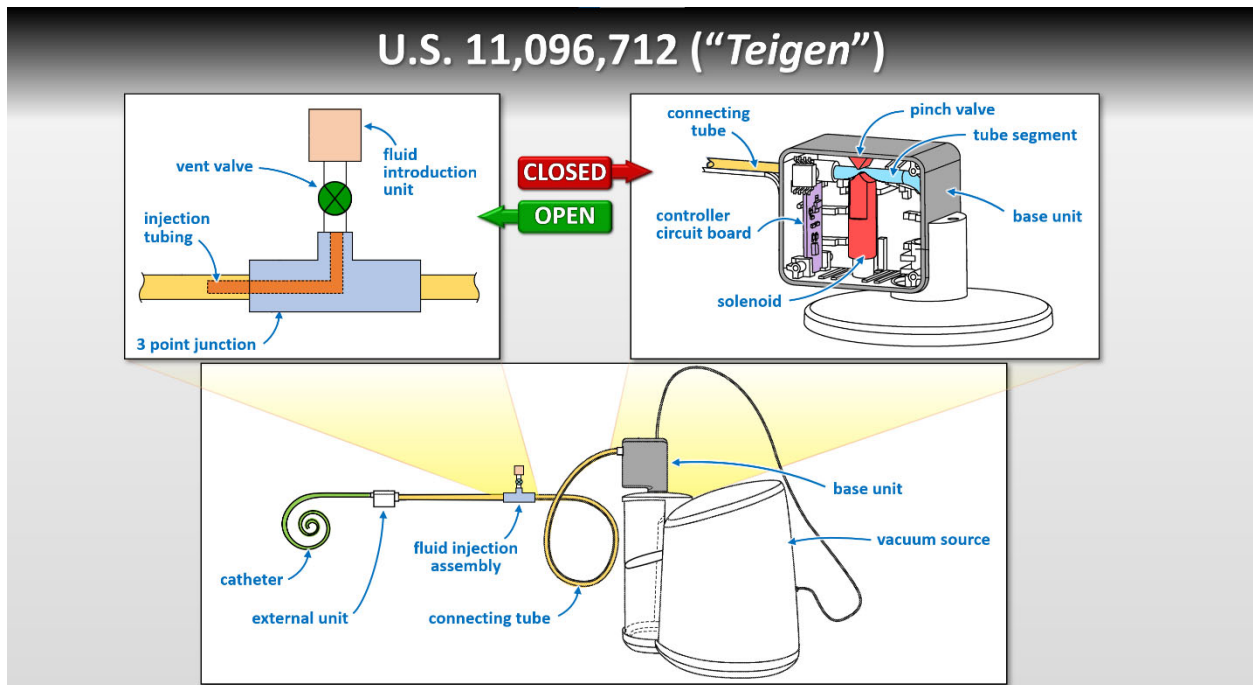
69. As illustrated in the following annotated diagrams of the disclosed Teigen system, operating the valves in serial demonstrates a “double-closed state.” Consistent with the disclosure of Teigen-Provl quoted above, the dynamic aspiration cycle begins with the vacuum (on-off) valve open and the vent (saline injection unit) valve closed:



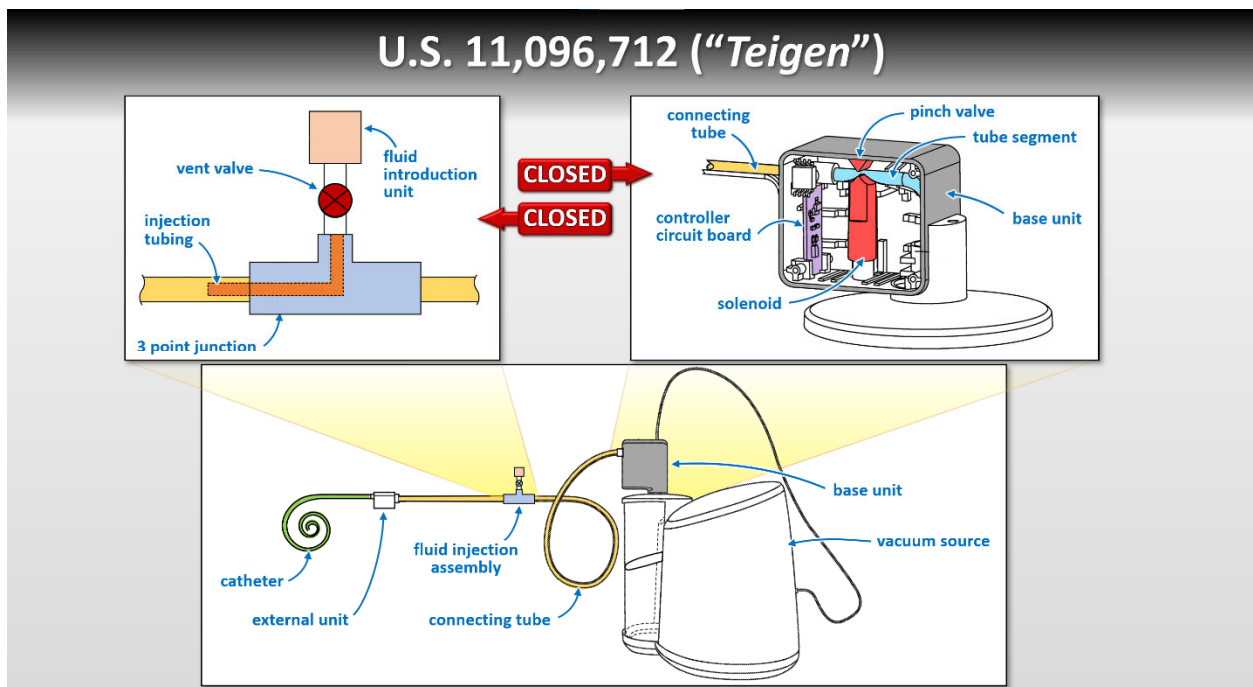
70. The system then **closes “the on-off valve to the pump,”** resulting in a first double-closed state before it **“opens the [vent] valve”**:



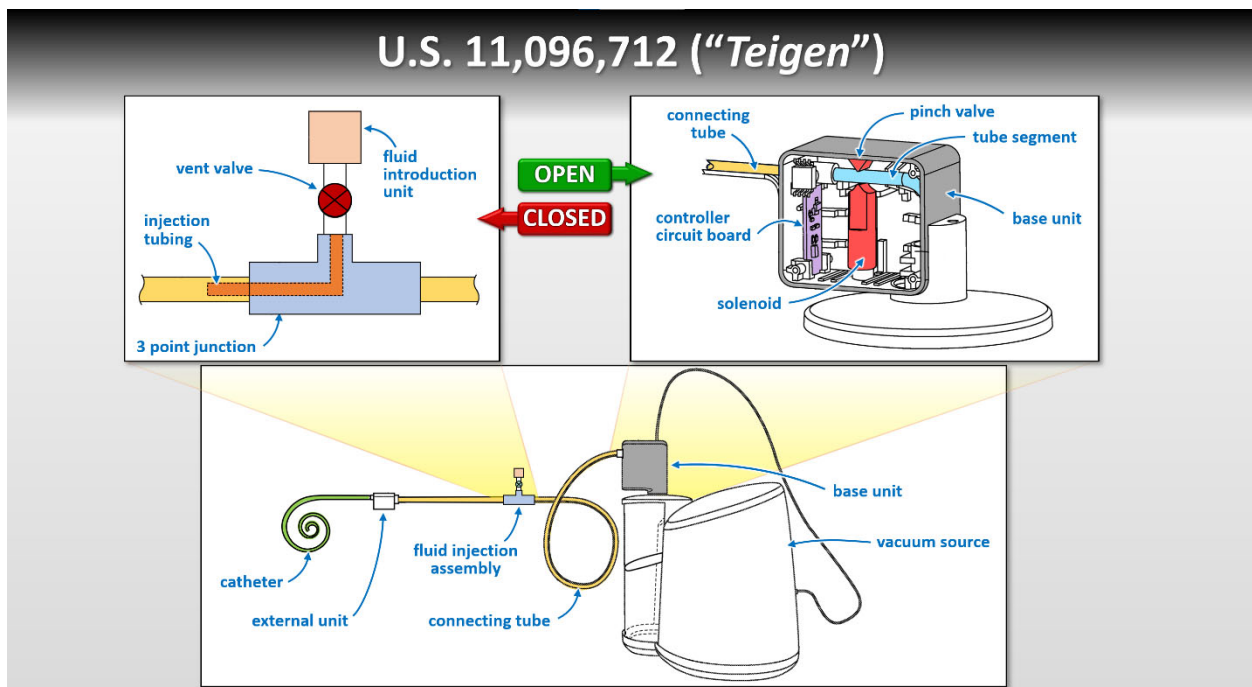
71. The system then opens “the valve 296 to the saline injection unit 290” to “partially relieve vacuum.” A person of skill in the art would have found it obvious that first closing the vacuum valve before turning on the vent/saline valve would be the most logical and effective way to “partially relieve vacuum.” Otherwise, the saline will be lost to the vacuum canister, reducing the effectiveness of the pressure differential created by the use of saline.



72. Then “after a short period of time the system will close [vent] valve 296,” resulting in a second “double-closed state.”



73. The system finally reopens the vacuum valve to reestablish the aspiration vacuum. Similarly, a person of skill in the art would have understood that it makes the most sense, and certainly would have been obvious, to first close the saline injection valve before reopening the vacuum valve. Otherwise, the saline will be evacuated through the open saline injection valve and the vacuum valve during the course of reestablishing the aspiration vacuum, leading to a substantial loss of saline and reducing the effectiveness of the pressure differential created by opening the vacuum valve.



74. Therefore, serial valve operation is at least an obvious way to conduct the valve operations expressly disclosed in Teigen, which leads to periods of double-closed states.

75. Patent Owner’s second argument fails for the same reasons as discussed in the previous section regarding the mischaracterization that closing the vacuum valve necessarily creates and results in forward flow. As explained above and admitted by Dr. Finol, even when the vacuum valve is closed and the saline valve is open (i.e., a vent-only state), Teigen-Prov1 “paragraph 64 teaches that the saline, quote, reduces, unquote, the vacuum, which necessarily means some level of vacuum remains in the catheter.” Ex. 1031 at 73:18-20. It follows that if the saline valve is instead closed along with the vacuum valve, i.e., a double-closed state, there would be even less relief of vacuum in the catheter because there would no longer be a relief of vacuum caused by the saline injection. Therefore, Patent Owner’s argument relies on the incorrect assumption that “introduction of a ‘double-closed’ state would cut off the vacuum source” and “would eliminate the ‘non-zero suction force at all times in catheter.’” PO Response at 49; Ex. 2014, ¶ 160.¹¹ A person of skill in the art would not avoid closing the vent valve for a brief period during the

¹¹ Patent Owner and Dr. Finol also misleadingly suggests that a “positive pressure pulse” equates to a “positive pressure.” PO Response at 49; Ex. 2014 at ¶¶ 160-161. It does not. Pressure pulse refers to a pressure differential: a positive pressure pulse indicates an increase of pressure whereas a negative pressure pulse corresponds to a decrease in pressure. Ex. 1007 at 15:13-23.

transition of the various valve configurations disclosed in Teigen, because a double-closed state does not lead to increased risk of distal migration of clot material more than the vent only state does. As such, including “double-closed state” in the serial operations of vacuum and vent valves is an obvious and natural way to implement the combination of Teigen ’712 and Grey.

VI. Claims 2-3 and 6-9 are Obvious in View of Teigen ’712 , Grey, and Rubenstein

76. Patent Owner and Dr. Finol further contest the obviousness of the “double-closed state” limitation in view of the Rubenstein reference. Patent Owner argues that (1) Rubenstein is not analogous art and (2) that Rubenstein doesn’t disclose a “double-closed state.” PO Response at 50-57; Ex. 2014, ¶¶ 169-183.

77. Patent Owner and Dr. Finol assert that “Rubenstein is not from the same field of endeavor as the ’883 Patent” because “Rubenstein provides aspiration in larger cavities” whereas “the ’883 Patent is directed to minimally invasive intravascular procedures for removing occlusions from blood vessels, such as small and fragile blood vessels in the brain.” PO Response at 50; Ex. 2014, ¶ 171. Patent Owner appears to be characterizing the field of invention of the ’883 Patent in the narrowest possible manner to exclude prior art that a person of skill in the art would consider in the field of designing catheters for use in medical procedures.

78. In my opinion, a person of skill in the art would understand that Rubenstein is in the same field as the ’883 Patent, at least because the ’883 Patent

expressly discloses that its catheter system “can be coupled with conventional aspiration catheters to significantly increase the efficacy of such catheter and pump systems,” and because Rubenstein specifically “relates to pumping systems that are used with catheters for drawing fluids and other viscous materials from a body,” which “is a conventional medical procedure.” Ex. 1001 at 3:30-32; Ex. 1011 at 1:6-18.

79. Patent Owner further argues that “Rubenstein is not reasonably pertinent to the problem faced by the inventors of the ’883 Patent.” PO Response at 52. Patent Owner again narrowly characterizes the problem to be solved as “efficiently and effectively macerating clot material while preventing forward flow that creates dangerous distal migration of a clot,” without citing to any specific support in the ’883 Patent. PO Response at 52.

80. To the contrary, the ’883 Patent’s stated goal is “to overcome the problems with the prior art systems, designs, and processes as discussed above,” including: “During conventional aspirations, it is common... at the distal opening of the aspiration catheter, a condition that can be referred to as coked or corking.” Ex. 1001 at 1:64-2:4, 3:5-6. Rubenstein similarly addresses “[t]he problem of clogging and traumatic injury... to be solved by the design and use of catheters,” explaining that “[p]rior art suction units presently in use essentially involve a catheter to which

is connected a suction pump for applying negative pressure thereto... As may be expected, the tip of the catheter frequently becomes clogged.” Ex. 1011 at 1:19-38.

81. Thus, it is my opinion that Rubenstein is in the same field of endeavor as the ’883 Patent, and is at least reasonably pertinent to the particular problem with which the inventor faced because it describes issues with clogged catheters and using alternative cycling of negative and positive pressure to overcome these problems. Ex. 1011 at 1:10-14, 1:26-27, 1:64-68.

82. Patent Owner’s argument that Rubenstein fails to disclose a “double-closed state” is also incorrect. In Rubenstein’s system, “cyclical reversals of pumping pressure are applied to the catheter connected thereto to have negative and positive pressure cyclically alternated.” Ex. 1011 at 1:10-14. As explained below and as conceded in the PO Response, Rubenstein discloses a rotary valve 46/18 which may be rotated between a first position (FIG. 2A) in which the catheter is fluidically connected with a vacuum line to provide a negative pressure in the catheter, to a second position (FIG. 2B), in which the vacuum line is disconnected from the catheter. Ex. 1011 at FIGs. 1, 2; PO Response at 54-56; Ex. 2014, ¶¶ 175-178. Similarly, Rubenstein discloses a rotary valve 60 which may be rotated between a first position (FIG. 2C) in which a fluid line is disconnected from the catheter, to a second position (FIG. 2D) in which the catheter is fluidically connected with the

fluid line to reduce the negative pressure in the catheter. Ex. 1011 at FIGs. 1, 2; PO Response at 54-56; Ex. 2014, ¶¶ 175-178.

83. Rubenstein explicitly describes the operation and rotational transition of these valves: “The valve 18 simply may involve a movable plug 46 having a connecting channel 48 and which is alternately rotated under the control of the timer 44 to have the channel 48 connect the tubing 30 to either the tubing 28 or the tubing 42... diagram B illustrates the movable plug 46 as having been rotated to have the channel 48 positioned to permit fluid flow between the tubing 42 and the tubing 30 such that positive pressure is applied to the catheter 16 connected to the hose 30.” Ex. 1011 at 3:21-36.

84. Rubenstein also explains: “The valve 60 **may be of the same type** as the valve 46.... Referring to FIG. 2, diagram C illustrates a movable plug 65 as being positioned to prohibit fluid flow through the valve 60. By comparison, diagram D illustrates the movable plug 65 as being positioned to allow fluid flow through the valve 60.” Ex. 1011 at 3:21-36.

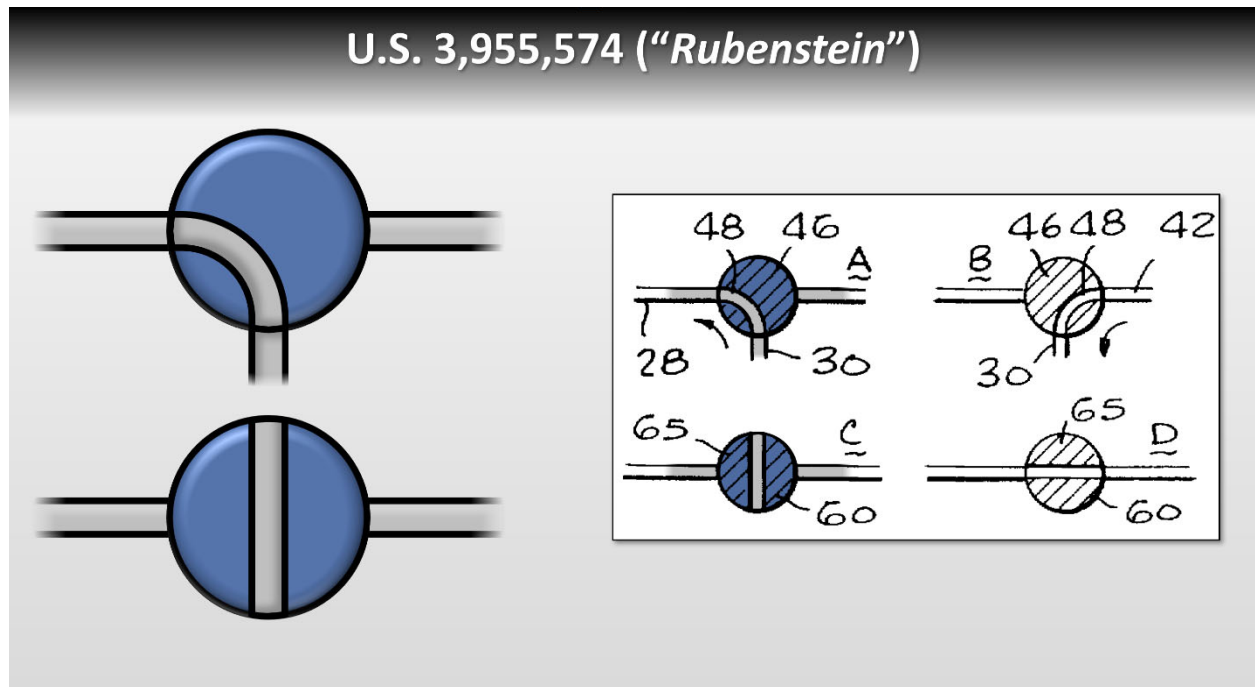
85. Patent Owner takes the position that it is simply “speculation” and “hypothesizing” that “the time that it would take to rotate the movable plugs within the valves would not be instantaneous.” PO Response at 56. Patent Owner further argues that Rubenstein’s **rotary valves** do not actually **rotate** between their different

positions, but instead, somehow have “an instantaneous transition that does not include any delay time.” PO Response at 57; Ex. 2014, ¶¶ 179-183.

86. A person of skill in the art would find these positions outlandish and contrary to basic physics and common sense. Patent Owner provides no explanation, indeed cannot provide any, of how such an “instantaneous transition” would be achieved. It is well-known, and explained in Rubenstein, that a rotary valve functions by rotating a connecting channel to different locations in order to connect and/or disconnect channels attached to the valve. Ex. 1011 at 3:21-26. Given the finite distance between the different positions, it requires a finite time period for the valve to rotate between different positions, which is by definition not instantaneous.

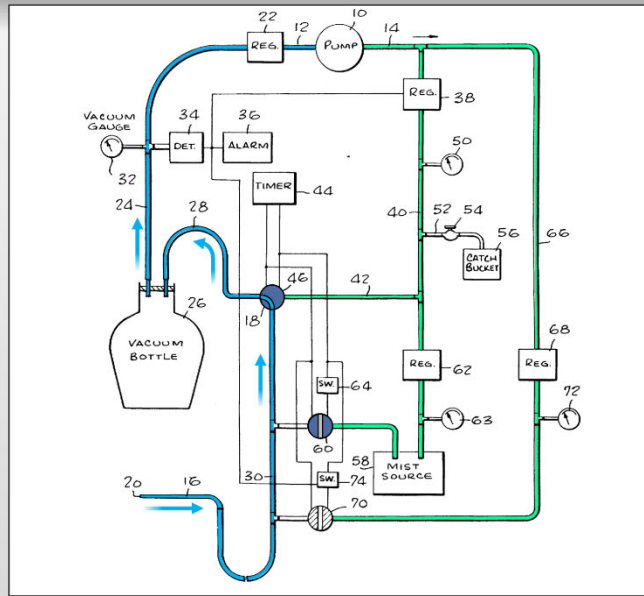
87. Rubenstein’s rotary valves are in a double-closed state when they are rotating between the positions where the connecting channels are aligned to fluid and vacuum channels, as illustrated in the following annotated diagrams of Rubenstein’s system. Consistent with the disclosure of Rubenstein discussed above, the rotary valves begin in a first position “A” and “C,” respectively, in which the

catheter is connected through a connecting channel 48 of valve 46/18¹² to the vacuum, but disconnected from the fluid line, which is closed off by valve 60:



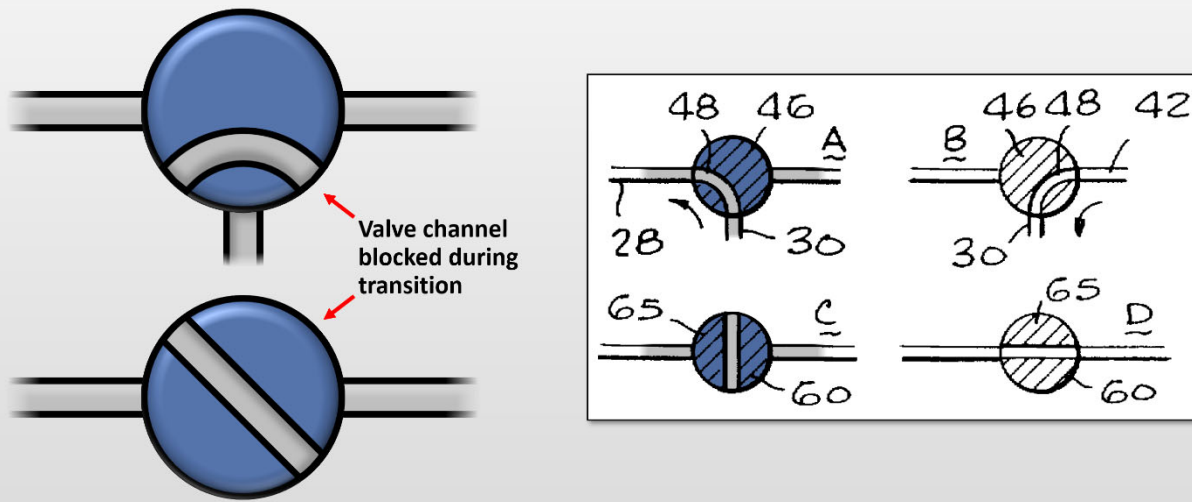
¹² Figure 2 of Rubenstein does not identify the valve numbering 18, but instead illustrates components of valve 18 including “a movable plug 46 having a connecting channel 48.” Ex. 1011 at 3:21-26.

U.S. 3,955,574 ("Rubenstein")

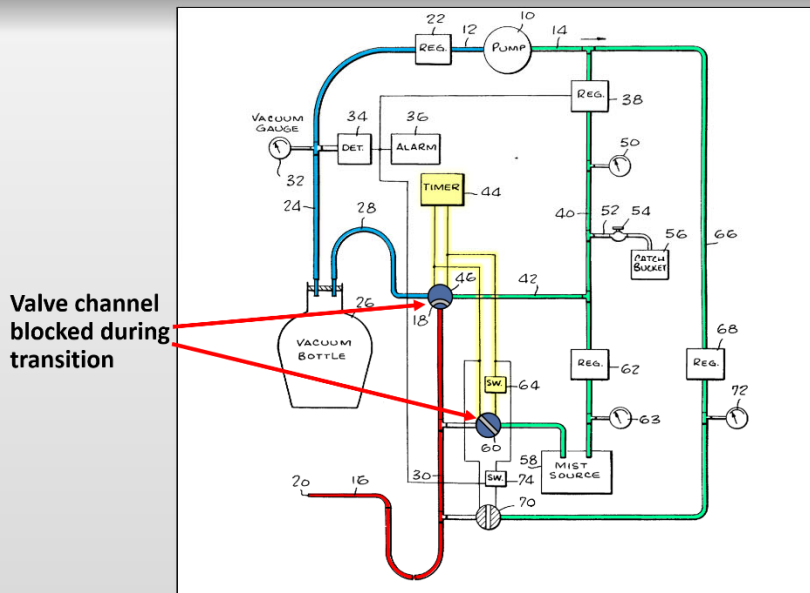


88. The Rubenstein system then rotates connecting channels in valves 46/18 and 60 from their first position towards a second position. A person of skill in the art would have understood that during this transition, the connecting channels are not aligned with either the vacuum or fluid line, and are therefore in a “double-closed state,” as illustrated below.

U.S. 3,955,574 ("Rubenstein")

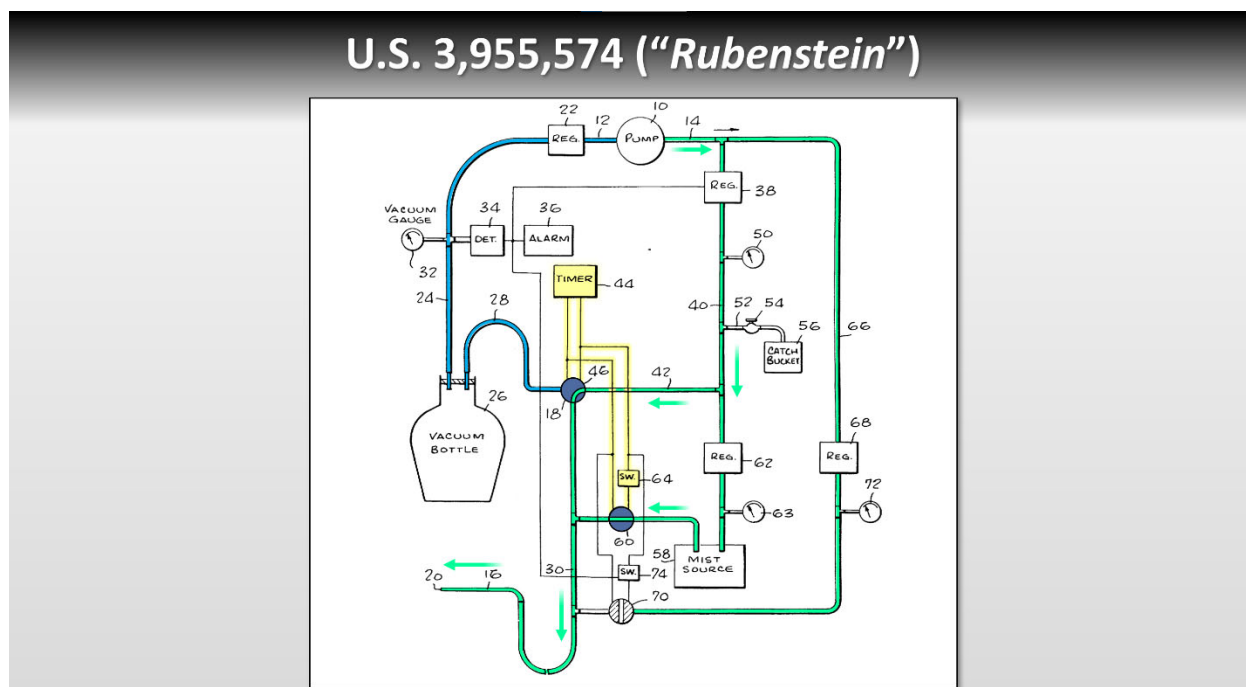
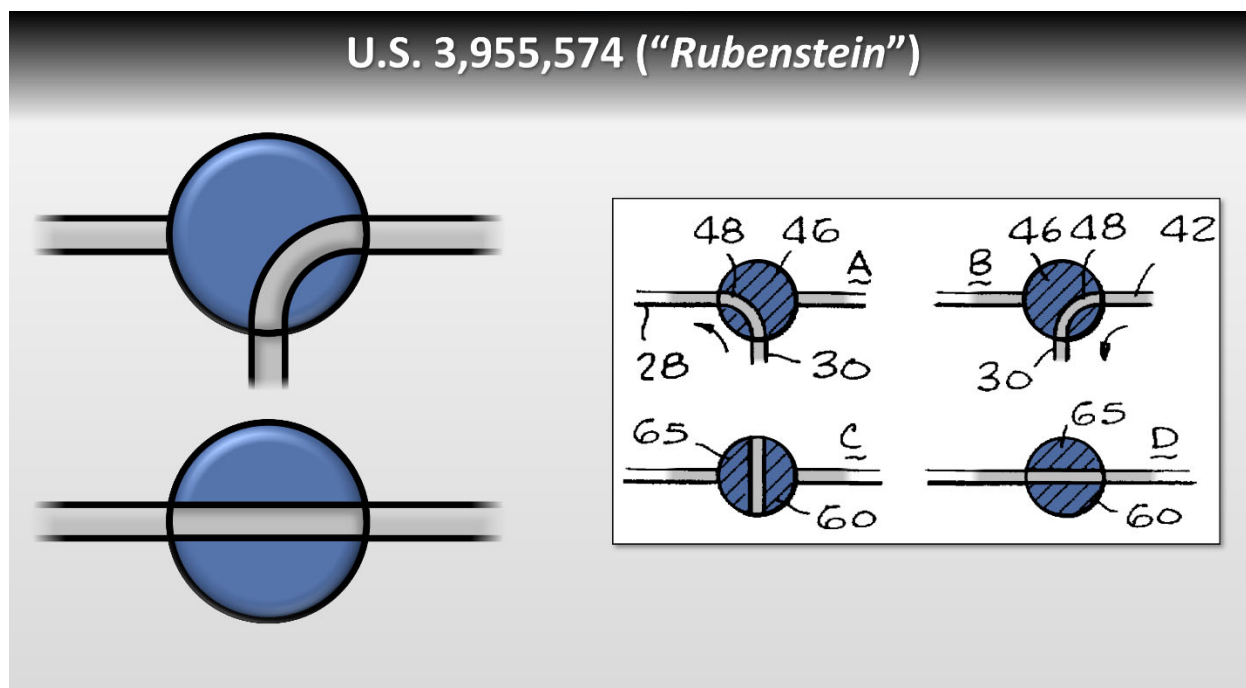


U.S. 3,955,574 ("Rubenstein")



89. Following the “double-closed state” transition period, the connecting channels of rotary valves 46/18 and 60 rotate to their second position “B” and “D,”

respectively, in which the catheter is connected to the fluid line and disconnected from the vacuum, as further illustrated below:



90. Therefore, a person of skill in the art would understand that Rubenstein discloses and/or renders obvious a “double-closed state” while the rotary valves are rotating between their first and second positions.

91. Finally, Patent Owner and Dr. Finol argue that a person of skill in the art would not be motivated to combine Rubenstein with Teigen ’712 and Grey, but provides no reasoning to support this position. PO Response at 57. I disagree, because a person of skill in the art would have found it obvious to modify the system in Teigen ’712 to adopt the valves disclosed in Rubenstein, which would result in a double-closed state during serial operation of the incorporated valves. A person of skill in the art would also find it obvious to employ Rubenstein’s time-controlled valve opening and closing because Rubenstein notes that “any cycle and ratio of negative and positive pressure can be used to satisfy a particular need” which would invite a person of skill in the art to optimize the positive and negative pressure system in Rubenstein to achieve optimal clot aspiration within the Teigen system. Ex. 1011 at 3:41-50; *see also id.* at 2:64-68 (disclosing certain example rotary valves that can be automated).

VII. Claims 10-12 are Obvious in View of Teigen ’712 and Grey

92. Patent Owner concedes that Claims 10-12 are not entitled to any earlier priority date than the filing date of the ’883 Patent. PO Response at 36, n. 5. Instead, Patent Owner contends that the combination of Teigen ’712 and Grey does not teach

“the recited **combination**” of a change in level of vacuum (ΔP) occurring within a limited time period (t). PO Response at 58 (emphasis in original); Ex. 2014, ¶ 163. Patent Owner’s argument fails because it solely relies on a non-limiting example of Grey to distinguish the claimed combination while ignoring the teaching of the prior art as a whole regarding improvement of clot removal in connection with both pressure differential and timing.

93. With respect to ΔP , Grey discloses that “the realized pressure differential (i.e., the magnitude of the difference between the maximum and minimum pressure achieved at the catheter tip) may be between 0 and -100 inHg.” Ex. 1010 at 13:4-6. It is undisputed that this pressure differential range fully encompasses the claimed ΔP ranges in Claims 10-12. Patent Owner argues that “-100 inHg is not enabled as it is an impossible level of vacuum to achieve on Earth.” PO Response at 58-59, n. 8; Ex. 2014, ¶ 164. Patent Owner confuses “pressure differential (i.e., the magnitude of the difference between the maximum and minimum pressure achieved at the catheter tip),” which is disclosed in Grey, with a “level of vacuum,” which Patent Owner alleges the failure of enablement. While Patent Owner may be correct the “vacuum on Earth is, at most, -29.9 inHg,” it does not follow that the pressure differential, “between the maximum and minimum pressure” must be limited to -29.9 inHg. A person of skill in the art would have understood, a pressurized fluid source, in fact disclosed in Grey, can increase the

pressure differential far exceeding the change between 0 inHg (atmospheric pressure) and full vacuum (-29.9 inHg). Ex. 1010 at 11:18-20 (“A larger magnitude of the positive pressure of the second aspirating medium may be used to increase the rate of change of suction force at the distal end of the catheter.”). Therefore, Grey discloses a pressure differential range that fully encompasses the claimed changes in the level of vacuum of “greater than approximately 15/20/25 inHg.”

94. With respect to timing, Patent Owner and Dr. Finol concede that Grey teaches “cycle times as low as 20 ms based on operating at 50 Hz.” PO Response at 59. As I have explained in my Original Declaration, and it is undisputed, that this cycle time of less than 20 ms falls within the scope of claimed timing of “no greater than approximately [50/30/20] ms.” Ex. 1005, ¶¶ 214, 219; PO Response at 59-60. Patent Owner merely argues that Petitioner failed to “connect Grey’s broad ΔP ranges with his separately disclosed frequencies.” PO Response at 60; Ex. 2014, ¶ 165.

95. Contrary to Patent Owner and Dr. Finol’s argument, a person of skill in the art would be motivated to combine the disclosed pressure differential ranges with the timing disclosed in Grey. Specifically, a person of skill in the art would have understood that a high-pressure differential generally speeds up the material fatigue of a clot as taught in Grey and would thus choose to apply a pressure differential above a minimal threshold value to facilitate clot extraction. Notably, Grey explains

that “[d]ifferent frequencies of cyclic aspiration may be used to improve clot clearance in comparison to static aspiration” and “higher frequencies are more effective.” Ex. 1010 at 10:28-29. Because Grey teaches both a higher pressure differential and a higher frequency are preferable, it would have been obvious for a person of skill in the art to apply the high-pressure differential disclosed at a high frequency to optimize “treatment efficacy” as directed by Grey. Ex. 1010 at 10:22-29, 11:18-20.

96. Patent Owner and Dr. Finol argue that the pressure profile examples of Grey (FIGs. 3A-3C) do not disclose a combination of pressure differential and timing as claimed. PO Response at 61 (“Grey discloses the combination of $\Delta P/t$, even at the maximum frequency of 6.3 Hz tested in Grey, the disclosed ΔP (-13.9 inHg) is less than the lowest claimed ΔP (i.e., at least -15 inHg).”); Ex. 2014, ¶ 166. But FIGs. 3A-3C are, as Patent Owner recognizes, just “example[s],” which do not limit the express disclosure of Grey.

97. To the contrary, Grey expressly contemplates a higher-pressure differential that increases both pressure differential and the rate of pressure change (i.e., faster change). Ex. 1010 at 12:1-3 (“If the second aspirating medium in Figure 3C operated at a positive pressure (e.g., 10 inHg) rather than atmospheric pressure, the *rate of pressure change* would *increase* due to the *increased pressure differential* between aspiration mediums.”). Additionally, Grey discloses that the

example Figure 3C used a manual valve operation. Ex. 1010 at 23:1-9 (disclosing that a third group label ‘Max Hz,’ shown in FIG. 3C, “where the experimenter cycled the system as fast as possible” by “manual[ly] opening and closing opening 216.”).

98. A person of skill in the art would find it obvious to achieve a higher frequency with improved rate of change using automatically controlled valves, such as the ones disclosed in Teigen ’712. The combination of high ΔP and faster rate can be readily achieved with a pressurized vent fluid at a frequency as expressly taught in Grey, and requires no more than simple automation of valves as disclosed in Teigen. In fact, Grey expressly encourages “increasing [cycle] frequency” for “more effective treatment” and increasing the vent fluid pressure when operating at increased frequencies, which would lead a person of skill in the art directly towards the claimed ranges. Ex. 1010 at 24:11-16, 12:1-7.

XIV. Secondary Considerations

99. It is my opinion that Patent Owner and Dr. Finol have not identified any persuasive evidence of secondary considerations of non-obviousness tied to the claimed invention of the ’883 Patent. Patent Owner fails to present any evidence that shows the claimed invention “has addressed a long-felt need for an effective treatment for patient with ischemic stroke.” Patent Owner further fails to demonstrate any nexus between any secondary considerations and any claimed features not disclosed in the prior art. Patent Owner also makes no effort to compare

any purported evidence of secondary considerations to the specific prior art combinations that render the challenged claims obvious. Further, Patent Owner's expert admits that dynamic aspiration was known in the art, and as such, I understand that the purported secondary indicia relied upon by Patent Owner would be equally applicable to those conventional techniques, and to the techniques taught in Gray and Teigen '712. Ex. 2014, ¶ 32.

100. Therefore, there is no objective evidence of non-obviousness that might warrant a finding that the challenged claims are patentable.

XV. Reservation of Rights

101. My opinions are based upon the information that I have considered to date. I reserve the right to supplement my opinions in the future to respond to any arguments raised by the owner of the '883 Patent and to consider new information that becomes available to me.

XVI. Declaration

102. I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true. I further understand that willful false statements and the like are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code. I declare under penalty of perjury that the foregoing is true and correct.

Executed on October 3, 2022.



Brian Brown