UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COOK MEDICAL LLC
Petitioner

v.

STONE BASKET INNOVATIONS LLC
Patent Owner

Case: IPR2016-00713

Patent 6,551,327

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,551,327

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Pursuant to 35 U.S.C. § 311, Petitioner hereby respectfully requests *inter partes* review of Claims 1-8 of U.S. Patent No. 6,551,327 ("the '327 Patent") (Ex. 1001), which issued on April 22, 2003. According to USPTO records, the current owner of the '327 Patent is Stone Basket Innovations LLC. Based on the prior art cited in this Petition, the challenged claims are unpatentable under 35 U.S.C. § 103 and should be cancelled.

I. REQUIREMENTS FOR PETITION FOR *INTER PARTES* REVIEW

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '327 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review of the '327 Patent.

B. Notice of Real Parties-In-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner states that Cook Group Incorporated, Cook Incorporated and Cook Medical Technologies LLC are real parties-in-interest with Petitioner Cook Medical LLC.

C. Notice of Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner states that the '327 Patent is the subject of a patent infringement lawsuit brought by the Patent Owner, Stone Basket Innovations LLC, in the United States District Court for the Eastern District

of Texas: *Stone Basket Innovations LLC v. Cook Medical LLC*, Case No. 15-CV-464.

D. Notice of Lead and Back-up Counsel and Service Information

Pursuant to 37 C.F.R. §§ 42.8(b)(3), 42.8(b)(4) and 42.10(a), Petitioner provides the following designation of counsel and service information:

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E. Fee for *Inter Partes* Review

Pursuant to 37 C.F.R. § 42.103, a payment of $23,000 will be charged to Deposit Account **130019** at the time of this filing. Should any further fees be required, the Patent Trial and Appeal Board ("the Board") is authorized to charge the above Deposit Account.

II. IDENTIFICATION OF CHALLENGED CLAIMS AND REQUESTED RELIEF

Pursuant to 37 C.F.R. § 42.104(b), Petitioner requests that the Board find that Claims 1-8 of the '327 Patent are unpatentable under 35 U.S.C. § 103 and should be cancelled.

III. OVERVIEW OF GROUNDS FOR CHALLENGE

This Petition involves a patent that should never have issued. The patent discloses a surgical extraction device comprising a handle, a sheath with a lumen, a support filament and a collapsible retrieval basket. During prosecution, the Examiner twice rejected the application after finding that the prior art disclosed each of the limitations of the claimed invention. The inventor then amended the claims to add a "sheath movement element" on a handle that opened and closed the collapsible basket by advancing or retracting a covering sheath. The inventor persuaded the Examiner that this limitation distinguished the claimed invention from the prior art.

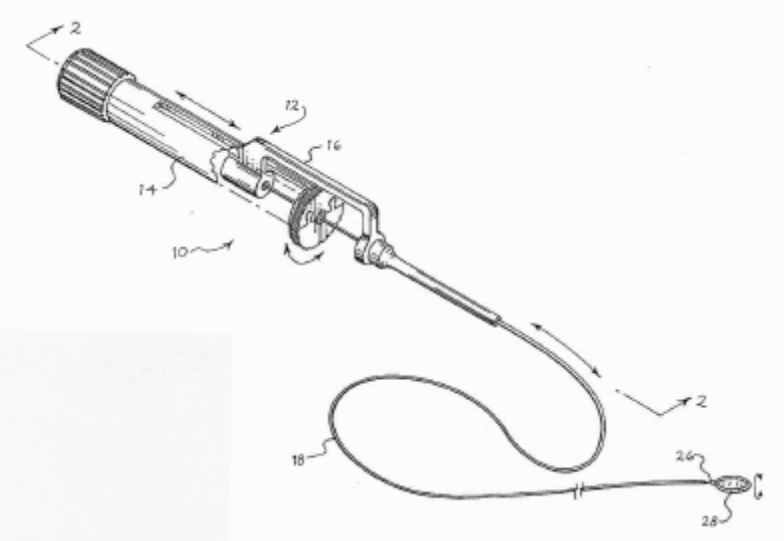
Yet, at the time of the 2001 filing, the handle with a "sheath movement element" was not novel at all. Not only did the element appear in several prior art patents, but it also was featured in stone extraction devices marketed by Cook and other companies in the 1990s. Indeed, at a deposition in a related district court proceeding, the inventor admitted that (1) the sheath movement element was not novel in 2001; and (2) he copied the handle containing the "sheath movement element" from a Cook device in drafting the drawings for his patent application.

Accordingly—and as detailed in Section VIII below—the prior art patents and publications cited in this Petition provide three separate grounds for finding Claims 1-8 of the '327 Patent unpatentable under 35 U.S.C. § 103.

IV. RELEVANT BACKGROUND

A. Technology Background

This Petition involves percutaneous surgical extractors, which are used to remove objects located within vessels of the body such as the urinary tract system. Ex. 1001 at 1:6-10. As depicted below, these devices generally contain a handle, a sheath with a lumen, a support filament and a collapsible retrieval basket or filter:



Id. at Fig. 1; Wagoner Decl. (Ex. 1028) at ¶ 46.

The purpose of the basket or filter is to trap biological material such as stones, clots, plaques and other particulates. Ex. 1001 at 1:5-10; Wagoner Decl. (Ex. 1028) at ¶¶ 61-64. The basket or filter is "collapsible" so that it can fit within the lumen of the sheath, but then expands to its fully operational shape when moved outside the sheath. Ex. 1001 at 4:45-54; Wagoner Decl. (Ex. 1028) at ¶¶

41-45. The physician will typically open the basket to surround a stone or other object, and then close the basket to "capture" the stone for removal. *Id.* at 46.

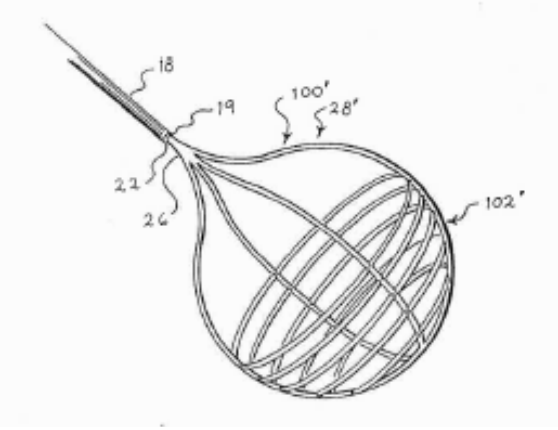
Prior to 2001, surgical extractors relied on two basic mechanisms to open and close the retrieval baskets or filters. *Compare* Ex. 1003, at 3:67-4:8 *with* Ex. 1005 at 4:22-37; Wagoner Decl. (Ex. 1028) at ¶¶ 47-55, 101-102. In one version, the physician opened and closed the basket by moving a wire connected to the basket through a fixed sheath. Ex. 1003 at 3:67-4:8; Wagoner Decl. (Ex. 1028) at ¶¶ 56-60, 101-102. In this version, the physician opened the basket by pushing it outside the sheath, and closed the basket by pulling it back into the sheath. *Id.*

In the second version, the physician opened and closed the basket by using a moveable sheath. Ex. 1005 at 4:22-37; Wagoner Decl. (Ex. 1028) at ¶¶ 56-60, 101-102. In this version, the physician used a "slider" to move the sheath forward to collapse the basket (and thereby close it), or to move the sheath backward to "free" the basket (and thereby open it). *Id.*

B. Summary of the '327 Patent

The '327 Patent issued on April 22, 2003 from an application filed on January 17, 2001. Ex. 1001. In its only independent claim (Claim 1), the patent discloses a stone extraction device consisting of a handle, a long wire called a "support filament" which has proximal and distal ends, a sheath with a lumen, and a collapsible basket attached to the support filament. *Id.* at 2:18-26, 3:41-49,

3:65-4:2, 4:30-35; Wagoner Decl. (Ex. 1028) at ¶ 68. The support filament runs through the lumen of the sheath and attaches to the handle at its proximal end and the basket at its distal end. Ex. 1001 at 2:31-38; Wagoner Decl. (Ex. 1028) at ¶ 68. The basket is formed by longitudinal and lateral filaments. Ex. 1001 at Figs. 9-11; Wagoner Decl. (Ex. 1028) at ¶¶ 67-68. It contains a "stone-entrance region" (**100**) (which consists of one or more large openings facing the distal end of the support filament) and a "stone-retention region" (**102**) (which consists of a plurality of smaller openings and is positioned opposite the distal end of the support filament):



Ex. 1001 at Fig. 10, 2:31-38, 4:29-35, 5:1-5, 6:10-11; Wagoner Decl. (Ex. 1028) at ¶¶ 65, 68. The large openings in the stone entrance region facilitate the entry of stones into the basket, while the smaller openings in the stone retention region facilitate the entrapment of stones. Ex. 1001 at 4:29-47; Wagoner Decl. (Ex. 1028) at ¶¶ 65, 68.

Claim 1 also discloses a slider that is part of the handle and connected to the sheath. *Id*. at 2:18-26. When the slider is moved in one direction, it advances the sheath over the basket, thereby "collapsing" the basket into the sheath. *Id*. at 3:65-4:8; Wagoner Decl. (Ex. 1028) at ¶ 68. When the slider is moved in the opposite direction, it withdraws the sheath from the enclosed basket, thereby allowing the basket to expand to its operational shape. Ex. 1001 at 3:41-49; Wagoner Decl. (Ex. 1028) at ¶¶ 66, 68.

The '327 Patent also has seven dependent claims that add minor limitations as set forth below.

C. The Prosecution History of the '327 Patent

On January 17, 2001, the named inventor, Avtar Dhindsa, filed a patent application that included eight claims. *See* Ex. 1002 at 15-34; Wagoner Decl. (Ex. 1028) at ¶ 69. On March 8, 2002, the Examiner issued a Non-Final Office Action rejecting all eight claims as anticipated or rendered obvious in view of U.S. Patent Nos. 6,165,200 ("Tsugita") and 5,201,740 ("Nakao"). Ex. 1002 at 52-59; Wagoner Decl. (Ex. 1028) at ¶¶ 70-72. The Examiner explained that Tsugita and Nakao taught "all of the limitations of the present invention," with the sole exception of certain limitations involving "an obvious matter of dimensioning" (*e.g.*, openings in the basket of "less than 2 mm") which the Examiner found to be non-patentable. Ex. 1002 at 55-56; Wagoner Decl. (Ex. 1028) at ¶¶ 70-72.

To overcome the rejection, the inventor submitted a response asserting that Tsugita did not invalidate the claims because it failed to teach a sheath that was "slideable with respect to the support filament, as required by Claim 1." Ex. 1002 at 72-73; Wagoner Decl. (Ex. 1028) at ¶ 73. The Examiner disagreed, finding that the claimed distinction did not distinguish Tsugita as invalidating prior art. Accordingly, on October 23, 2002, the Examiner issued a Final Office Action rejecting the claims. Ex. 1002 at 88-93; Wagoner Decl. (Ex. 1028) at ¶ 73.

To overcome the second rejection, the inventor proposed an amendment adding as a new limitation a "handle comprising a sheath movement element":

> a handle comprising a sheath movement element, wherein movement of the sheath movement element in a first direction advances the sheath and causes the basket to at least partially collapse inside the lumen of the sheath, and wherein movement of the sheath movement element in a second direction retracts the sheath and causes the basket to expand to an operational shape outside the lumen of the sheath;

Ex. 1002 at 99-100; Wagoner Decl. (Ex. 1028) at ¶ 74. The inventor claimed that this amendment would "overcome the rejection using Tsugita et al as reference." Ex. 1002 at 95.

The Examiner agreed. *Id.;* Wagoner Decl. (Ex. 1028) at ¶ 74. Consequently, on January 27, 2003, the Examiner issued a Notice of Allowance

based on his finding that the prior art did not teach a sheath movement element. Ex. 1002 at 107; Wagoner Decl. (Ex. 1028) at ¶ 75.

This finding was incorrect. Wagoner Decl. (Ex. 1028) at ¶ 80. As shown below, the prior art included a wide range of printed publications that disclosed each of the elements of the '327 Patent, including stone extractors with "handle[s] comprising sheath movement element[s]." *Id*.

V. CLAIM CONSTRUCTION

For purposes of this Petition only, the terms of the '327 Patent should be given their broadest reasonable construction in light of the specification of the '327 Patent. 37 C.F.R. § 42.100(b).

A. Construction of Claim Terms

All claim terms not specifically addressed in this section have been accorded their broadest reasonable interpretation as understood by one of ordinary skill in the art and consistent with the specification of the '327 Patent. Petitioner submits that the following term may need to be construed in connection with this IPR:

1. "Sheath Movement Element"

Claim 1 of the '327 Patent states that "movement of the sheath movement element in a first direction advances the sheath and causes the basket to at least partially collapse inside the lumen of the sheath" and that "movement of the sheath movement element in a second direction retracts the sheath and causes the basket

to expand to an operational shape outside of the lumen of the sheath." Ex. 1001 at 6:19-27. Accordingly, under its broadest reasonable construction, the term "sheath movement element" means "any part of the device that can be used to move the sheath to open and close the basket." Wagoner Decl. (Ex. 1028) at ¶¶ 77-78.

VI. PERSON OF ORDINARY SKILL IN THE ART

The '327 Patent relates to the design of surgical extraction devices used by physicians. A person of ordinary skill in the art relevant to the '327 Patent would be either (1) a medical doctor with an MD degree performing percutaneous minimally invasive procedures within vessels in the human body and having at least 3 years knowledge and experience in the materials engineering and mechanical engineering aspects of percutaneously administered devices, or (2) an engineer with a Ph.D. or higher degree in materials or mechanical engineering with at least 3 years knowledge and experience of the medical requirements and uses of percutaneously administered devices. Wagoner Decl. (Ex. 1028) at ¶¶ 24-27.

VII. RELEVANT PRIOR ART

This Petition relies primarily on the following three prior art patents:

(1) **Tsugita** (which discloses each of the material limitations of '327 Patent except the "sheath movement element");

(2) U.S. Patent No. 6,168,603 ("**Leslie**") (which discloses each of the material limitations of the '327 Patent except the lateral and longitudinal basket filaments); and

(3) U.S. Patent No. 5,496,330 ("**Bates I**") (which discloses a sheath movement element and most of the material limitations of the '327 Patent).

The Petition also relies on marketing materials published by Cook and Boston Scientific Corporation, as well as on several other prior art patents, including U.S. Patent Nos. 6,099,534 ("Bates II"), 6,096,053 ("Bates III"), 6,179,859 ("Bates IV"), 6,364,895 ("Greenhalgh") (Ex. 1015), and 4,790,812 ("Hawkins"). The primary references are described below.

A. Tsugita

Tsugita (Ex. 1003), which issued on December 26, 2000, was filed on October 19, 1999, prior to the January 17, 2001 filing date of the '327 Patent, and is therefore available as prior art under pre-AIA 35 U.S.C. § 102(e). Tsugita was cited and considered by the Examiner during prosecution of the '327 Patent.

Like the '327 Patent, Tsugita discloses a percutaneous device comprising a handle, a support filament with proximal and distal ends, a sheath with a lumen, and a collapsible filter or basket attached to the support filament. Ex. 1003 at 7:52-67; Figs. 1, 3, 8A and 8B; Wagoner Decl. (Ex. 1028) at ¶¶ 82-89. The support filament (or guidewire) attaches to the handle at the proximal end and runs through the lumen of the sheath to the distal end where it attaches to a collapsible filter. *Id*.

The filter is formed by longitudinal filaments or struts (**54**) and lateral filaments (**60**) that are part of a mesh:

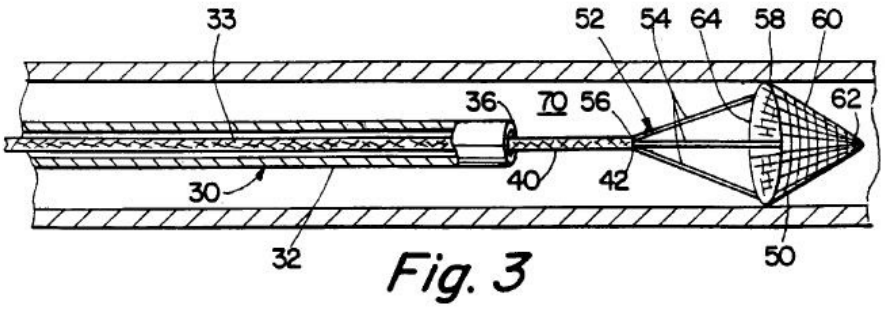


Fig. 3

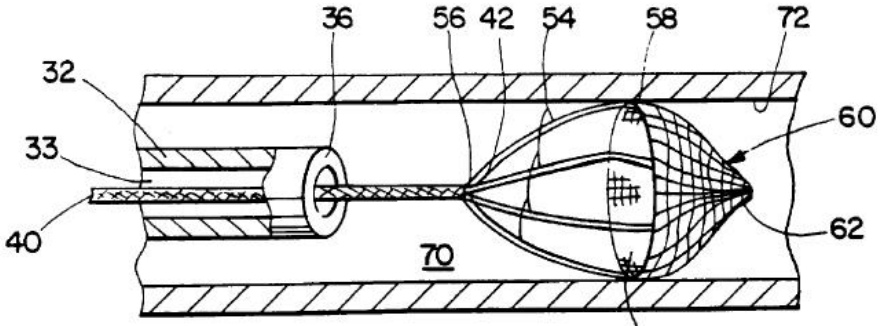


Fig. 8A

Ex. 1003 at 7:52-8:5, 8:39-55, 12:16-23, Figs. 3 and 8A; Wagoner Decl. (Ex. 1028) at ¶¶ 82-84, 119-124.

As shown above, the four longitudinal filaments create an open region (*i.e.*, a particle entrance region) that faces the distal end of the guidewire. *Id*.; Wagoner Decl. (Ex. 1028) at ¶¶ 117-118. This open region facilitates the entry of a particulate into the basket. Ex. 1003 at 10:1-11 and Figs. 8A and 8B; Wagoner Decl. (Ex. 1028) at ¶¶ 115-116. The lateral filaments are positioned substantially in the distal region of the filter (*i.e.*, the particle retention region), and they create

smaller openings that facilitate the entrapment of the particulate. Ex. 1003 at 8:56-61, 10:1-11, Figs. 8A and 8B; Wagoner Decl. (Ex. 1028) at ¶ 115-124. The filter remains in a compressed form while inside the sheath (32), and it can be opened by using the guidewire to push it outside the sheath. Ex. 1003 at 3:65-4:8; Wagoner Decl. (Ex. 1028) at ¶¶ 89-93.

Thus, Tsugita teaches each of the material limitations of Claim 1 of the '327 Patent, except a "handle comprising a sheath movement element." Wagoner Decl. (Ex. 1028) at ¶¶ 81, 84, 124. Instead of a moveable sheath, Tsugita relies on the guidewire to move the basket in and out of the sheath. Ex. 1003 at 3:65-4:8; Wagoner Decl. (Ex. 1028) at ¶ 89.

B. Leslie

Leslie (Ex. 1004), which issued on January 2, 2001, was filed on November 6, 1997, prior to the January 17, 2001 filing date of the '327 Patent, and is therefore available as prior art under pre-AIA 35 U.S.C. § 102(e). Leslie is listed on the face of the '327 Patent, but it was not cited or discussed by the Examiner during prosecution of the '327 Patent.

Like the '327 Patent, Leslie discloses a stone extraction device comprising a handle, a support filament (*i.e.*, cable (**90**) and rod (**91**) together) with proximal and distal ends, a sheath with a lumen, and a collapsible basket attached to the support filament. Ex. 1004 at Figs. 1, 10 and 11, 4:37-49, 4:64-67, 6:54-67, 10:19-36;

Wagoner Decl. (Ex. 1028) at ¶¶ 158-164. The cable attaches to a rod in the handle at the proximal end and runs through the lumen of the sheath to the distal end where it attaches to a collapsible basket. Ex. 1004 at Figs. 1, 10, 11; Wagoner Decl. (Ex. 1028) at ¶ 158-164.

As shown below, Leslie discloses a retrieval basket with proximal and distal ends formed by two to four "strands" (**22**) that radiate from the distal end of the cable or support filament (**25**):

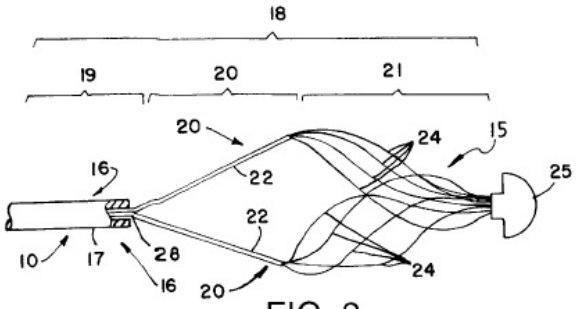


FIG. 2

Ex. 1004 at Figs. 2, 7, 8 and 9, 4:22-26, 4:44-49; 9:56-10:4; Wagoner Decl. (Ex. 1028) at ¶¶ 170-173. The two to four strands divide into a plurality of filaments (**24**), that each extends to the distal end of the basket. Ex. 1004 at 6:23-38; Wagoner Decl. (Ex. 1028) at ¶¶ 170-173, 175-176. The two to four strands create an open area (*i.e.*, a stone entrance region) in the proximal part of the basket (**20**) that faces the distal end of the support filament. Ex. 1004 at 7:1-6, 6:18-20, Fig. 3; Wagoner Decl. (Ex. 1028) at ¶¶ 170-174. This open area facilitates the entry of stones into the basket. *Id*. The more numerous filaments in the distal region of the

basket (*i.e.*, the stone retention region) (**21**) create smaller openings that facilitate the entrapment of stones and prevent stone migration. Ex. 1004 at 7:1-6, 18-20, Fig. 3; *see also* Ex. 1004 at 7:20-24, 9:56-61; Wagoner Decl. (Ex. 1028) at ¶¶ 177-182.

Like the '327 Patent, Leslie also discloses a handle comprising a sheath movement element (*i.e.*, a "slider" (**14**)) that opens and closes the basket by moving the sheath:

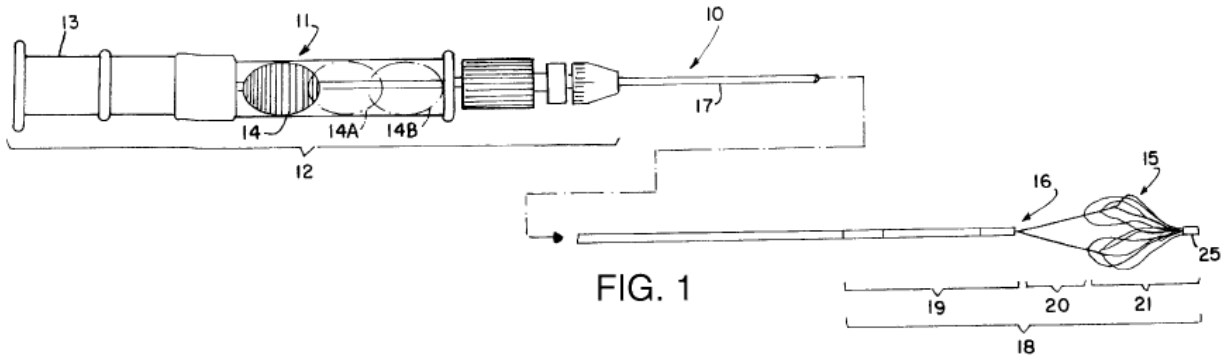


FIG. 1

Ex. 1004 at 4:37-44, 4:59-64, 6:4-10, 6:52-63, 7:17-20, Figs. 1, 2 and 3; Wagoner Decl. (Ex. 1028) at ¶¶ 165-169. When the physician introduces the distal end of the extractor into the urinary tract system, the sheath (**17**) covers the basket to maintain its compressed form. *Id*. When the extractor is positioned next to a stone, the physician can move the slider from position **14B** to position **14A** to retract the sheath and thereby open the basket. *Id*. at Fig. 2; 4:20-26, 7:1-6, 7:17-20. Once the stone enters the basket, the physician can move the slider from position **14A** to **14B** to advance the sheath and thereby close the basket:

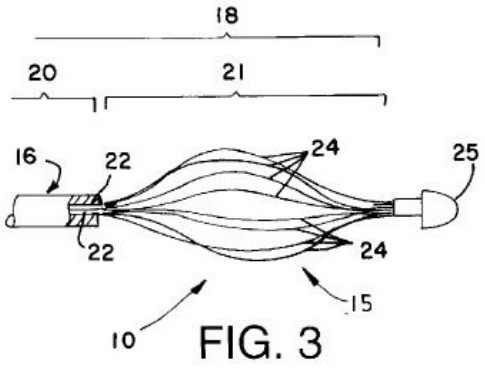


FIG. 3

Ex. 1004 at 7:20-24, 7:33-38, Fig. 3; Wagoner Decl. (Ex. 1028) at ¶¶ 165-169.

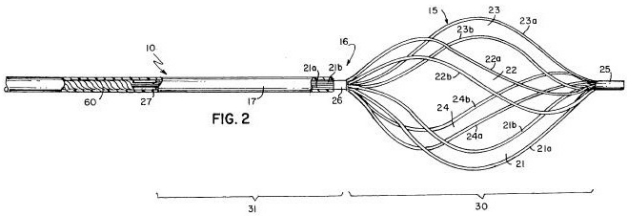
Thus, Leslie teaches all of the limitations of Claim 1 of the '327 Patent, except a "set of lateral basket filaments extending between the longitudinal filaments" of the basket. Wagoner Decl. (Ex. 1028) at ¶¶ 152, 176.

C. Bates I

Bates I (Ex. 1005) issued on March 5, 1996, which is prior to the January 17, 2001 filing date of the '327 Patent, and therefore constitutes prior art under pre-AIA 35 U.S.C. § 102(b). Bates I is listed on the face of the '327 Patent, but it was not cited or discussed by the Examiner during prosecution of the '327 Patent.

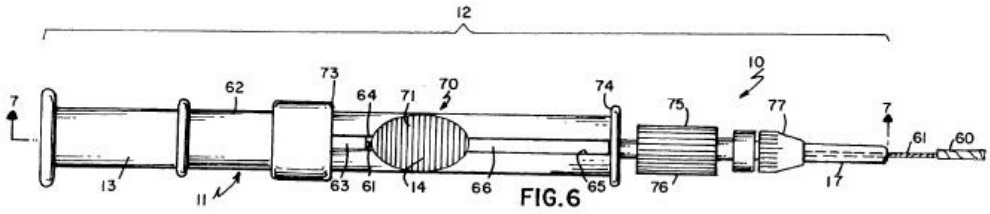
Like the '327 Patent, Bates I discloses a stone extraction device comprising a handle, a support filament (*i.e.*, cable (**60**) and rod (**61**) together) with proximal and distal ends, a sheath with a lumen, and a collapsible basket attached to the distal end of the support filament. Ex. 1005 at 5:57-61; Figs. 2, 3, 6 and 7; Wagoner Decl. (Ex. 1028) at ¶¶ 205-212.

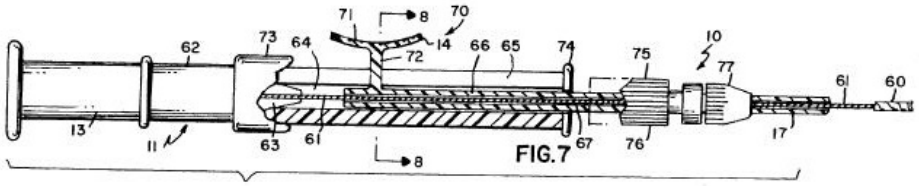
As shown below, Bates I discloses a collapsible retrieval basket formed by four pairs of widely-spaced parallel strands (**21-24**) extending from the distal end of the support cable:



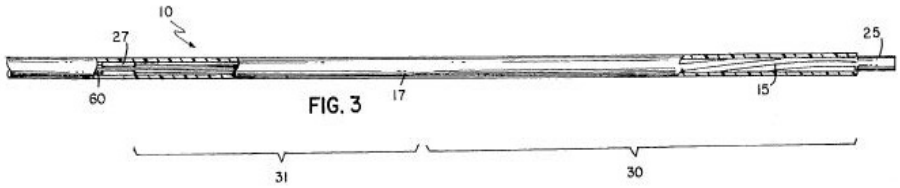
Ex. 1005 at Figs. 2, 4 and 5; Wagoner Decl. (Ex. 1028) at ¶¶ 212, 215. Each pair of strands follows a helical path to the distal end of the basket. Ex. 1005 at 2:3-10, 6:23-38, Figs. 8, 9; Wagoner Decl. (Ex. 1028) at ¶¶ 212, 215. When the basket is in an open position, the spacing between the four parallel strands creates an open region. Ex, 1005 at 4:29-37, Figs. 2 and 4; Wagoner Decl. (Ex. 1028) at ¶¶ 205-206, 215. When the basket is "compressed," the spacing between the parallel strands decreases, which facilitates the entrapment of stones. Ex. 1005 at 4:34-38; Fig. 5; Wagoner Decl. (Ex. 1028), at ¶¶ 205-206, 215.

Bates I also discloses a handle comprising a sheath movement element (*i.e.*, a "slider" (**14**)) that opens and closes the basket by moving the sheath (**17**).





Ex. 1005 at 3:46-50, 4:25-38, Figs. 6-7; Ex. 1006 at 5:12-27; Wagoner Decl. (Ex. 1028) at ¶¶ 213-216. As Bates I explains, the basket (**15**) is initially "compressed" within the sheath (17) at the distal end of the device:



Ex. 1005 at 4:22-25; Fig. 3. When the distal end is then positioned next to a stone, the physician can move the slider (**14**) proximally to retract the sheath (**17**) and thereby open the basket:

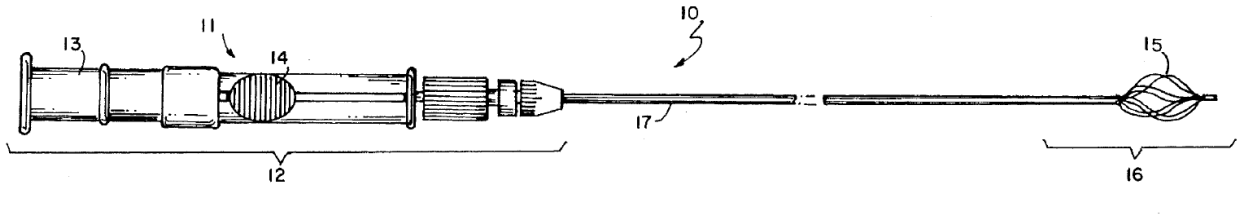


FIG.1

Id. at 4:26-33; Fig. 1; Wagoner Decl. (Ex. 1028), at ¶¶ 213-216.

The large openings between the filaments allow the stone to enter the basket. Ex. 1005 at 4:29-34, Fig. 1. Once the stone enters the basket, the physician can then move the slider forward to advance the sheath over the basket and thereby entrap the stone. Ex. 1005 at 4:33-38, Fig. 3; Wagoner Decl. (Ex. 1028) at ¶¶ 213-

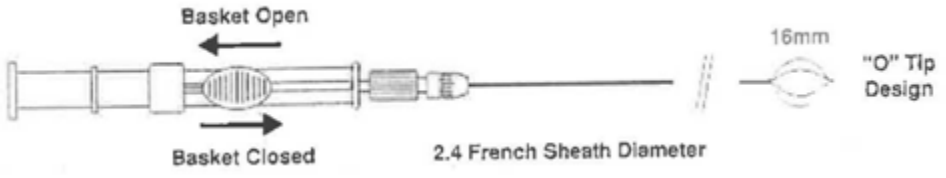
216. In this way, the sheath moves relative to the basket, while the basket remains immobile—just as in the '327 Patent. Wagoner Decl. (Ex. 1028) at ¶¶ 213-216.

Thus, Bates I discloses a stone extractor with a sheath movement element and a collapsible basket formed by longitudinal filaments radiating from the distal end of the support filament. Wagoner Decl. (Ex. 1028) at ¶ 204.

D. The "Sheath Movement Element" Prior Art

As shown above, Leslie and Bates I are two prior art patents that clearly disclose a "handle comprising sheath movement element" in which a moveable sheath opens and closes a collapsible basket. Bates II makes the same disclosure. Ex. 1006 at 5:12-30; Wagoner Decl. (Ex. 1028) at ¶¶ 56-58, 103-108; (Leslie, Bates I and Bates II are collectively referred to as the "SME Prior Art Patents"). But these references are not alone. In the nine years prior to the filing date of the '327 Patent, several companies marketed extractors with handles containing "sliders" that moved the sheaths to open and close the retrieval baskets. Wagoner Decl. (Ex. 1028) at ¶¶ 59-60, 109-113.

For example, in this period, Boston Scientific marketed its Microvasive line of stone extractors comprising a handle with a slider that could open and close the basket by advancing or retracting the sheath:



Ex. 1008 at 5-9; Wagoner Decl. (Ex. 1028) at ¶¶ 59-60, 111-112.

Similarly, in the same period, Cook marketed a "Unidex" handle for its stone extractors (depicted below) that featured the same slider and moveable sheath. Exs. 1009, 1010.

Ex. 1010 at 2-3; Wagoner Decl. (Ex. 1028) at ¶¶ 59-60, 109-110.

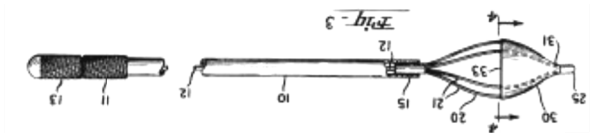
In a 1993 publication, Cook explained that the Unidex handle "permits the *basket itself to remain immobile*. *It is the sheath that is pulled back to reveal the basket*." Ex. 1009 at 1 (emphasis added). The same publication explained that the "immobile" basket "enhances placement and decreases the likelihood that the stone will become dislodged while closing the basket." *Id.* Cook's publications further show that the company used the Unidex handle with its Atlas and Helical Extractors as early as 1993 and continued to use the handle with its NCircle extractors in the late 1990s—all prior to the filing date of the '327 Patent. Exs. 1009, 1010; Wagoner Decl. (Ex. 1028), at ¶¶ 59-60, 109-110.

Thus, like Leslie, Bates I and Bates II, the Boston Scientific and Cook publications (collectively, "Sheath Movement Element Prior Art" or "SME Prior Art") constitute prior art publications disclosing a sheath movement element.

Wagoner Decl. (Ex. 1028) at ¶¶ 112-114. The Boston Scientific and Cook publications, which are available as prior art under pre-AIA 35 U.S.C. § 102(b), were not listed on the '327 Patent, and they were not cited or considered by the Examiner.

E. The "Retrieval Basket" Prior Art

The prior art in 2001 also included extensive literature dealing with the configuration of collapsible retrieval baskets, including several patents. Wagoner Decl. (Ex. 1028) at ¶¶61-64. Many of these patents featured baskets with a "parachute" configuration in which the distal end of the basket has a much larger number of filaments or wires than the proximal end:



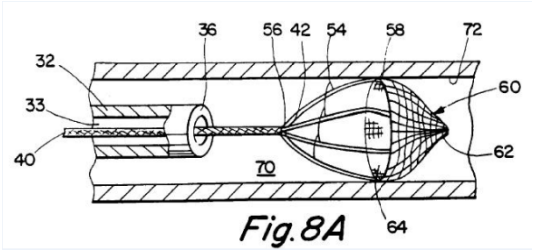


Fig. 8A

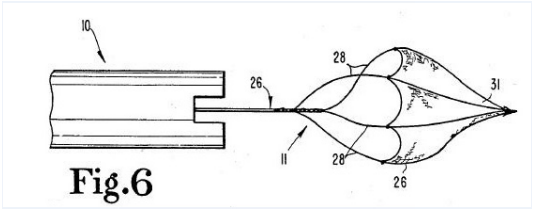


Fig.6

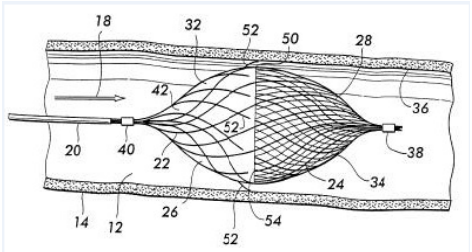


FIG. 3

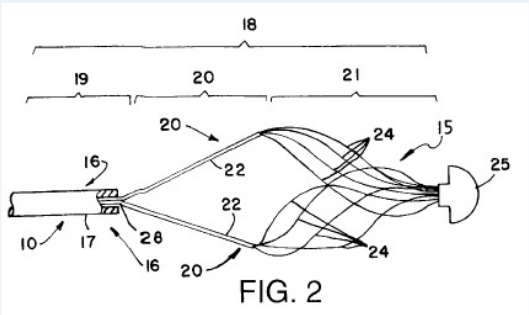


FIG. 2

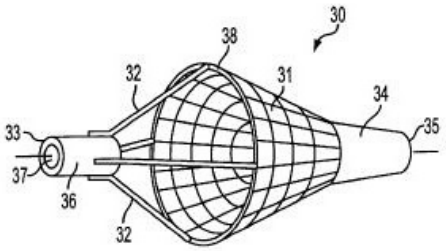


FIG. 2A

Fogarty (Ex. 1017) at Fig. 3; Hawkins (Ex. 1015) at Fig. 6; Leslie (Ex. 1004) at Fig. 2; Tsugita (Ex. 1003) at Fig. 8A; Greenhalgh (Ex. 1014) at Fig. 3; Bates IV (Ex. 1013) at Fig. 2A; Wagoner Decl. (Ex. 1028) at ¶¶ 61-64.

In this parachute style, the proximal end of the basket (which faces the distal end of the guidewire or support filament) has larger openings because of the smaller number of filaments. Wagoner Decl. (Ex. 1028) at ¶¶ 61-64. These openings serve as the point of entry for the target stones, clots or other objects. *Id.* By contrast, the distal end of the basket has much smaller openings (because of the larger number of filaments), and it can therefore serve as the "retention region" to capture the target objects. *Id.*

In several of the prior art baskets, the distal end of the structure features a set of longitudinal filaments radiating from the distal end of the support filament and a set of lateral filaments (sometimes in the form of a wire or fabric mesh) extending between the longitudinal filaments:

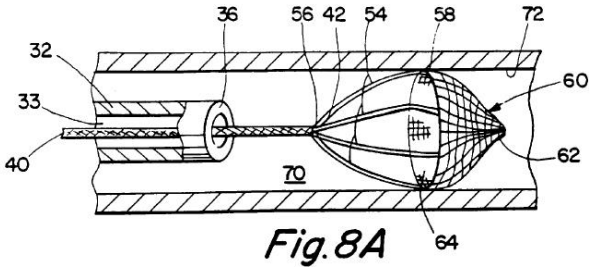


Fig. 8A

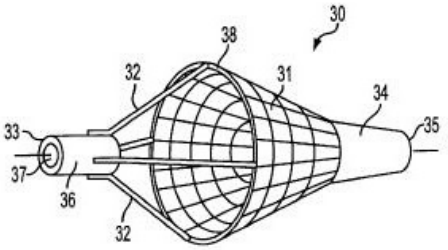
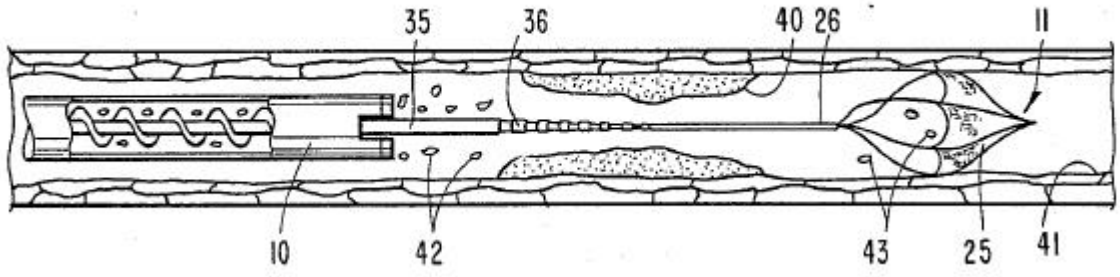


FIG. 2A

Tsugita (Ex. 1003) at Fig. 8A; Bates IV (Ex. 1013) at Fig. 2A; *see also* Hawkins (Ex. 1015) at Fig. 6; Bates II (Ex. 1006) at Fig. 6; Wagoner Decl. (Ex. 1028) at ¶¶ 61-64, 119-123, 176. This use of lateral and longitudinal filaments creates a "net" with smaller openings that are better able to retain smaller clots, stones and other objects (**43**), as shown below.



Hawkins (Ex. 1015) at Fig. 11; Wagoner Decl. (Ex. 1028) at ¶¶ 61-64.

VIII. SPECIFIC GROUNDS FOR PETITION

In light of the disclosures detailed below, Claims 1-8 of the '327 Patent are unpatentable and should be cancelled on the following grounds.

No.	Ground	Prior Art	Exhibit Nos.	Claims
1	103(a)	**Tsugita** and the **SME Prior Art**	Ex. 1003 and Exs. 1004-1006, 1008-1010	1-8
2	103(a)	**Leslie** and any of	Ex. 1004 and Exs. 1003,	1-8

No.	Ground	Prior Art	Exhibit Nos.	Claims
		Tsugita, Bates II or **Bates IV**	1006, 1013	
3	103(a)	**Bates I** and either **Tsugita** or **Bates IV**	Ex. 1005 and Exs. 1003 or 1013	1-8

A. Ground 1: Claims 1-8 are Obvious over Tsugita in View of the Sheath Movement Element Prior Art

The combination of Tsugita and any one of the SME Prior Art references discloses each limitation of Claims 1-8.

1. Claim 1

The combination of Tsugita and any one of the SME Prior Art references invalidates Claim 1 of the '327 Patent. Wagoner Decl. (Ex. 1028) at ¶¶ 80-81. As noted above, during prosecution of the '327 Patent, the Examiner twice rejected the application based on the prior art, including (principally) Tsugita. The Applicant then amended Claim 1 to add a handle comprising a "sheath movement element" that opened or closed the collapsible basket by advancing or retracting a covering sheath. Ex. 1002 at 99-100. The Examiner agreed that the proposed amendment would "overcome the rejection using Tsugita et al. as a reference." *Id*. at 95.

Accordingly, the addition of this limitation was material to the patentability of the claimed invention. *See* MPEP 706.02. Indeed, the prosecution history unmistakably shows that "but for" the addition of this amendment, the Examiner would not have issued the patent. Wagoner Decl. (Ex. 1028) at ¶¶ 94-95.

a. The Sheath Movement Element Was Well-Known in the Prior Art.

Notwithstanding the inventor's claims to the contrary, a handle comprising a sheath movement element was well-established in the prior art. Wagoner Decl. (Ex. 1028) at ¶¶ 96-100. Indeed, each of the stone extraction devices in the SME Prior Art (Leslie, Bates I, Bates II, and the Cook and Boston Scientific publications) disclosed a "handle comprising a sheath movement element" that caused the basket to open and close by moving the sheath backward or forward. *See* Exs. 1004-10; Wagoner Decl. (Ex. 1028) at ¶¶ 107-114.

Not surprisingly, therefore, in the related district court litigation, the named inventor admitted at his deposition that the addition of a handle comprising a sheath movement element did not confer any novelty on the claimed invention:

> Q. . . . Had you reviewed this amended language before it was submitted to the patent office?
>
> A. Yes, I believe I reviewed it with my attorney.
>
> Q. And you were aware, were you not, at this time, that there was nothing novel about a sheath movement element . . .
>
> **THE WITNESS:** ***I realize there is nothing novel about it***.

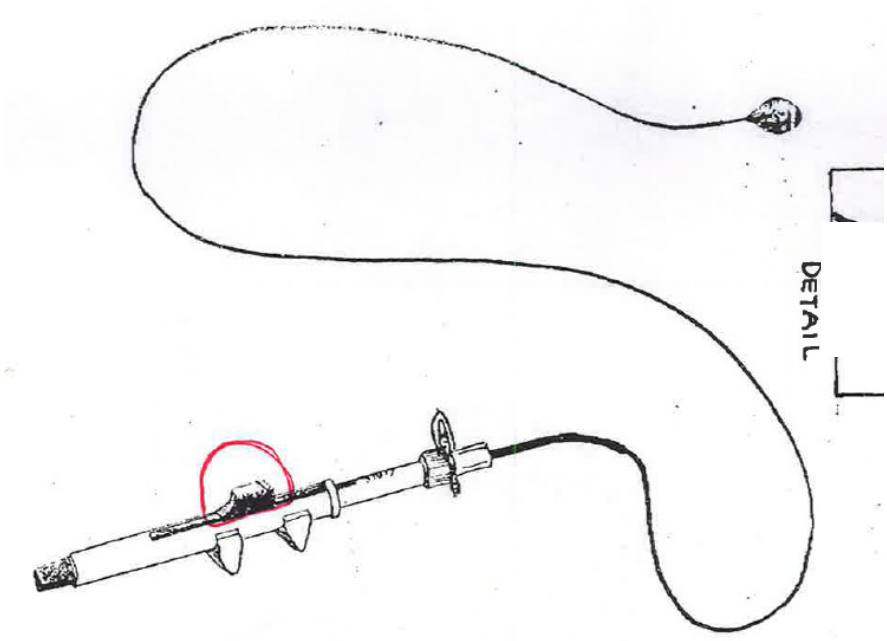
Ex. 1011 at 142 (emphasis added) (objections omitted); Wagoner Decl. (Ex. 1028) at ¶ 110.

The inventor further admitted that in drafting the figures depicting a "handle comprising a sheath movement element" for his patent application he simply copied the same element from Cook's NCircle stone extractor:

> Q. . . . Did you show [the artist] either the Boston Scientific or the Cook device to provide a model for what's depicted on the page bearing Bates-stamp number 658?
>
> A. This, I believe, was the Cook basket handle.
>
> Q. All right. And in the middle of the handle there is a dark, a darkened protuberance. Do you see what I'm referring to?
>
> A. Yes.
>
> Q. What's your understanding of that?
>
> A. ***That is what moves the sheath over the basket. That is what exposes and closes the basket.***
>
> Q. And was this based on the Cook device?
>
> **THE WITNESS:** ***This is a Cook handle.***

Ex. 1011 at 112-13 (emphasis added) (objections omitted); Wagoner Decl. (Ex. 1028) at ¶ 110.

This testimony can be corroborated by simply comparing the drawing the inventor submitted for his patent application (Ex. 1012 at Dhindsa 000568) with the NCircle device that Cook marketed in 1997 (Ex. 1010):



Ex. 1012.

Ex. 1010.

Such a comparison shows that the handles in the depicted devices are identical. Wagoner Decl. (Ex. 1028) at ¶ 110.

Thus, by his own admission, the inventor relied entirely on prior art to add the very limitation that the Examiner found to confer patentability over Tsugita. Wagoner Decl. (Ex. 1028) at ¶ 110. Based on this admission alone, the added limitation cannot be sufficient to "patentably distinguish [the claimed invention] over the prior art." MPEP 706.02; Wagoner Decl. (Ex. 1028) at ¶ 110.

b. Motivation to Combine

A person having ordinary skill in the art in 2001 would have had both general and specific motivations to combine Tsugita's disclosures (which focused on capturing emboli within blood vessels) with any one of the stone extraction devices disclosed in the SME Prior Art Patents. Wagoner Decl. (Ex. 1028) at ¶¶ 86-87, 125-128. On a general level, one of ordinary skill in the art would have been motivated to combine references disclosing surgical devices addressing the common problem of capturing and removing objects from body passageways. Wagoner Decl. (Ex. 1028) at ¶¶ 86-87, 125-128. For example, Hawkins (Ex. 1015) is directed to a surgical device for the removal of "objects, particularly blood clots, gallstones and kidney stones, purulent material and arthroma" from a "body passageway or cavity." Ex. 1015 at 3:9-16; Wagoner Decl. (Ex. 1028) at ¶¶ 86-87, 125-128. Indeed, as Dr. Wagoner explains, prior art patents routinely (1) disclosed devices designed to capture and remove objects from *both* blood vessels *and* the urinary tract system, or (2) cited to prior art in both areas. *See, e.g.*, Hawkins (Ex. 1015) at 3:9-16; Tran (Ex. 1023) at 1:29-45; Phan (Ex. 1024) at 1:36-43; Wagoner Decl. (Ex. 1028) at ¶¶ 86-87, 125-128.

On a more specific level, one of ordinary skill in the art would have been motivated to combine Tsugita with any of the SME Prior Art references to address the problem of captured stones becoming dislodged when the physician moved the

basket in an effort to close it. Wagoner Decl. (Ex. 1028) at ¶¶ 125-128; Ex. 1010 at 2. As shown above, it was well known in 2001 that a moveable sheath would allow the basket to remain immobile while it was being opened or closed. *Id*. This, in turn, "enhance[d] placement and decrease[d] the likelihood that the stone will become dislodged while closing the basket." *Id*. The moveable sheath thus provided a solution to the problem of stones becoming dislodged because of a non-stationary basket.[1] *Id.*

Accordingly, the combination of Tsugita with any one of the SME Prior Art Patents renders Claim 1 obvious. Wagoner Decl. (Ex. 1028) at ¶¶ 80-81, 128.

2. Claim 2

Claim 2 of the '327 Patent requires the stone-retention region to define an internally concave surface facing the first end portion of the support filament.

1 These same motivations also apply to other claims and limitations in the '327 Patent that expressly deal with the sheath movement element. These claims and motivations include Limitation 1B (specifying a sheath that is "slideable" with respect to the support filament), Claim 7 (specifying a sheath movement element that causes the basket to completely collapse inside the lumen) and Claim 8 (specifying that the sheath movement element comprises a handle with a "grip" and a "slide"). Wagoner Decl. (Ex. 1028) at ¶¶ 86-87, 125-128.

Tsugita discloses such a concave surface as shown in, for example, Figure 8A below:

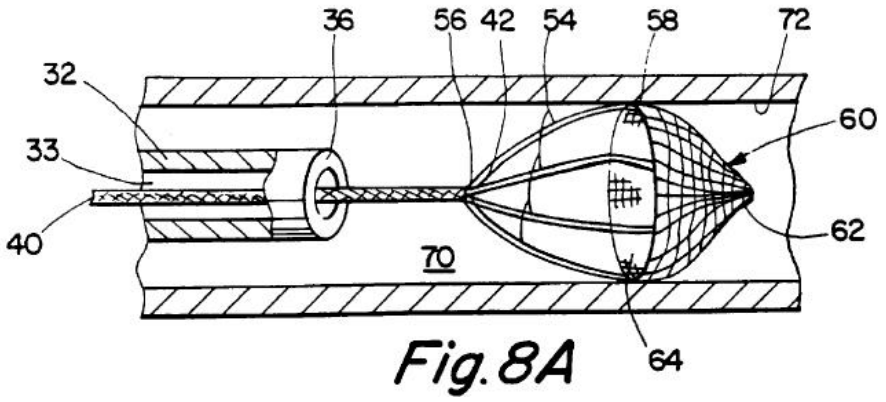


Fig. 8A

Ex. 1003 at 12:47-55, Fig. 8A; Wagoner Decl. (Ex. 1028) at ¶¶ 129-130.

3. Claims 3, 4 and 6

Claims 3 and 6 are directed to the size of the second openings of the stone-retention region (*i.e.*, smaller than 2 mm and 5 mm in minimum dimension, respectively), and Claim 4 is directed to the size of the first opening of the stone-entrance region (*i.e.*, larger than 2 mm in minimum dimension).

Tsugita discloses the use of mesh with holes (second openings) at 0.06-0.10 mm in dimension, which is smaller than 2 mm (Claim 3) and 5 mm (Claim 6). Ex. 1003 at 9:5-8 ("*[a]n exemplary embodiment of the mesh has . . . a pore [second opening] size of 60-100 μm*").

Moreover, one of ordinary skill in the art would have found it obvious to design a basket with holes within the claimed ranges. Wagoner Decl. (Ex. 1028) at ¶¶ 134-137. It was well known in 2001 that the diameter of fragmented kidney

stones ranged from 2-10 mm. Bates III (Ex. 1007) at 8:59-60; Wagoner Decl. (Ex. 1028) at ¶¶ 134-137. It was also well known that the openings in a basket or filter could be designed to capture "particles of a targeted size." Tsugita (Ex. 1003) at 8:59-61; Bates III (Ex. 1007) at 8:59-65; Wagoner Decl. (Ex. 1028) at ¶¶ 134-137.

Accordingly, as the Examiner noted during prosecution, "it would have been an obvious matter of dimensioning to one of ordinary skill in art to produce a web or mesh having holes sized within the range claimed." Ex. 1002 at 55-56, 91; Wagoner Decl. (Ex. 1028) at ¶¶ 134-137. Indeed, at his deposition, the inventor conceded that the specific dimensions used in Claims 3, 4 and 6 were "*arbitrary numbers that I picked*," and not based on any "scientific study." Ex. 1011 at 191-92 (emphasis added). Wagoner Decl. (Ex. 1028) at ¶¶ 134-137.

4. Claim 5

Claim 5 of the '327 Patent requires the support filament and basket to be free of attachment to the sheath, such that the entire basket is movable into the lumen of the sheath. Ex. 1001 at 6:53-55. As noted above, Tsugita or any one of the SME Prior Art Patents discloses this limitation. *See*, *e.g.*, Tsugita (Ex. 1003) at 4:49-56; Leslie (Ex. 1004) at 4:37-44, 4:59-64, Figs. 1, 4; Bates I (Ex. 1005) at 4:22-25, Fig. 3; Wagoner Decl. (Ex. 1028) at ¶¶ 141-143.

5. Claim 7

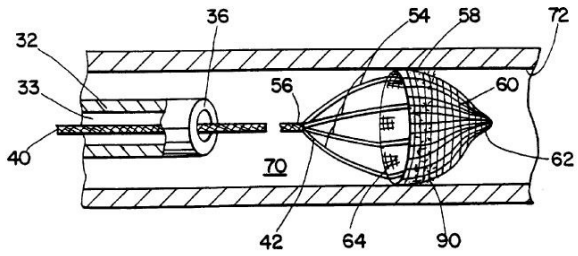
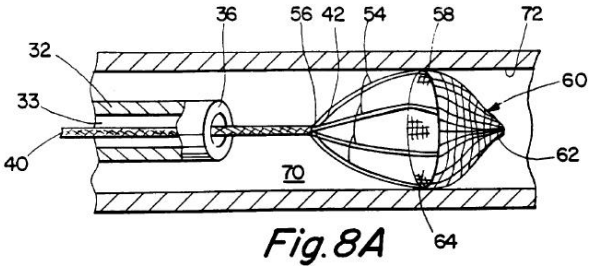
Claim 7 requires movement of the sheath movement element in the first direction to cause the basket to completely collapse inside the lumen of the sheath. Ex. 1001, at 6:58-60. As explained above, any one of the SME Prior Art Patents teaches that a sheath movement element can move distally to cause the retrieval basket to collapse completely. *See*, *e.g.*, Leslie (Ex. 1004) at 4:37-44, 4:59-64, Figs. 1, 4; Bates I (Ex. 1005) at 4:22-25, Fig. 3; Wagoner Decl. (Ex. 1028) at ¶ 144.

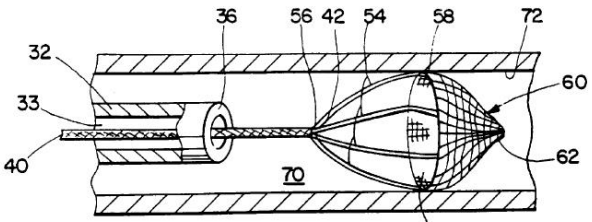
6. Claim 8

Claim 8 of the '327 Patent recites that the sheath movement element comprises a slide, wherein the handle comprises a grip, and wherein the slide is mounted for translation relative to the grip. Any one of the patents in the SME Prior Art discloses this limitation. *See*, *e.g.*, Leslie (Ex. 1004) at 4:37-44, 4:59-64; 6:4-10, 6:52-63; 7:17-20; Figs. 1, 2 and 3; Bates I (Ex. 1005) at 4:22-25, Fig. 3; Wagoner Decl. (Ex. 1028) at ¶¶ 146-151. For example, Leslie teaches that "[t]he surgical extractor 10 includes a handle 11 at a proximal end 12 having a base 13 and a slider 14. A physician can grasp the base 13 in the palm in his or her hand and manipulate the slider 14 with his or her thumb." Ex. 1004 at Fig. 1, 5:60-66; Wagoner Decl. (Ex. 1028) at ¶¶ 146-151.

The table below demonstrates how Tsugita in view of the SME Prior Art teaches each of the limitations of Claims 1-8 of the '327 Patent.

'327 Patent Claim Elements	**Tsugita (Ex. 1003) in view of the SME Prior Art (Exs. 1004-1006, 1008-1010)**
1. An endoscopic stone-extraction device comprising:	Leslie (Ex. 1004) at 1:10-13 ("*an extractor for removing . . . calculi that can form in the biliary and urinary systems*"); Bates I (Ex. 1005) at Abstract; Wagoner Decl. (Ex. 1028) at ¶¶86-87.
1A. a support filament comprising a first end portion and a second end portion;	Tsugita (Ex. 1003), at 7:59-62 ("*[t]he guidewire 40 . . . [has] a distal end 42 and a proximal end 44*") and Fig. 1; Wagoner Decl. (Ex. 1028) at ¶¶ 88-89.
1B. a sheath comprising a lumen, the support filament disposed in the lumen such that the sheath is slideable with respect to the support filament;	Tsugita (Ex. 1003) at 4:1-8 ("*the guidewire is pushed distally [inside the sheath]. The expansion frame exits the lumen . . . the guidewire is pulled proximally to withdraw the filter assembly . . . closing the frame as the filter assembly is pulled into the sheath*."); 7:58-65 and Fig. 1; Leslie (Ex. 1004) at Figs. 4 and 11, 10:60-62 ("*the slider 14 and the sheath 17 move relative to the rod 91*"; Bates I (Ex. 1005) at Abstract, 3:36-50, 4:22-38, Figs. 2, 3, 6 and 7; Wagoner Decl. (Ex. 1028) at ¶ 89.
1C. a collapsible stone-extraction basket carried by the first end portion of the support filament and receivable within the lumen of the sheath;	Tsugita (Ex. 1003) at 7:66-8:6 ("*attached on or near the distal end 42 of the guidewire 40 is an expandable filter assembly 50*"), 4:5-8 ("*the guidewire is pulled proximally to withdraw the filter assembly . . . closing the frame as the filter assembly is pulled into the sheath*."), 4:49-50; Wagoner Decl. (Ex. 1028) at ¶¶ 90-93.
1D. a handle comprising a sheath movement element, wherein movement of the sheath movement element in a first direction advances the sheath and causes the basket	Leslie (Ex. 1004) at Figs. 1 and 4; 4:38-44, 4:59-63, 5:7-14, 6:3-10, 6:56-59 ("*the physician moves the slider 14 from position 14B to the position 14 in FIG. 1. This retracts the sheath 17 . . . of the basket assembly 18*"), 7:34-36 ("*the physician advances the sheath 17 distally and*

'327 Patent Claim Elements	**Tsugita (Ex. 1003) in view of the SME Prior Art (Exs. 1004-1006, 1008-1010)**
to at least partially collapse inside the lumen of the sheath, and wherein movement of the sheath movement in a second direction retracts the sheath and causes the basket to expand to an operational shape outside the lumen of the sheath;	*reduces the volume of the retrieval basket 15*"); Bates I (Ex. 1005) at Abstract, 3:36-50, 4:22-38, Figs. 2, 3, 6 and 7; Ex. 1006 at 5:12-30; Ex. 1008 at 5-9; Ex. 1009 at 1; Ex. 1010 at 2-3; Wagoner Decl. (Ex. 1028) at ¶¶ 94-114.
1E. the basket, when expanded to the operation shape outside the lumen of the sheath, comprising a stone-entrance region and a stone-retention region, the stone-entrance region comprising a first opening sized to admit a stone into the basket, the stone-retention region comprising a plurality of second openings, all of the second openings being smaller than the first opening;	 Fig. 8B Tsugita (Ex. 1003) at 3:56-64, Figs 8A and 8B; Wagoner Decl. (Ex. 1028) at ¶¶ 115-116.
1F. the first opening facing the first end portion of the support filament, the stone-retention region positioned on a side of the basket opposite the first end portion of the support filament;	 Fig. 8A Tsugita (Ex. 1003) at Figs. 8A and 8B; Wagoner Decl. (Ex. 1028) at ¶¶ 117-118.
1G. wherein the basket comprises a set of longitudinal basket filaments	Tsugita (Ex. 1003) at 12:48-56, Figs. 8A and 8B; Wagoner Decl. (Ex. 1028) at ¶¶ 119-124.

'327 Patent Claim Elements	**Tsugita (Ex. 1003) in view of the SME Prior Art (Exs. 1004-1006, 1008-1010)**
radiating from the first end portion of the support filament and a set of lateral basket filaments extending between the longitudinal basket filaments, the lateral basket filaments positioned substantially entirely in the stone-retention region of the basket.	 *Fig. 8A*
2. The invention of claim 1 wherein the stone-retention region defines an internally concave surface facing the first end portion of the support filament.	Tsugita (Ex. 1003) at 12:47-56; In Fig. 8A above, "*[t]he filter mesh 60 has a substantially hemispherical shape*"); Wagoner Decl. (Ex. 1028) at ¶¶ 129-130.
3. The invention of claim 1 wherein the second openings are all smaller than 2 mm in minimum dimension.	Tsugita (Ex. 1003) at 8:59-61, 9:5-8 ("*[a]n exemplary embodiment of the mesh has . . . a pore [second opening] size of 60-100 μm*"); Wagoner Decl. (Ex. 1028) at ¶¶ 131-137.
4. The invention of claim 3 wherein the first opening is larger than 2 mm in minimum dimension.	Tsugita (Ex. 1003) at 8:59-61 ("*[a]n appropriate mesh is selected, having a pore size[d] [to] . . . capturing therein undesired particles of a targeted size*."); Bates III (Ex. 1007) at 8:59-60 ("*[o]nce fragmented, the pieces of the stone can be about 2 mm to 10 mm in diameter*"). Wagoner Decl. (Ex. 1028) at ¶¶ 131-137.
5. The invention of claim 1 wherein the support filament and basket are free of attachment to the sheath, such that the entire basket is movable into the lumen of the sheath.	Tsugita (Ex. 1003) at 4:49-56 ("*[t]he devices are compressed into the lumen of the sheath prior to use . . . [a]fter use, the guidewire is pulled proximally. . . compressing them back into the lumen*"). Leslie (Ex. 1004) at 6:4-10 and Fig. 4; Bates I (Ex. 1005) at 1:32-38, 3:41-45, 5:62-65, Figs. 3, 4 and 5; Wagoner Decl. (Ex. 1028) at ¶¶ 138-144.

'327 Patent Claim Elements	**Tsugita (Ex. 1003) in view of the SME Prior Art (Exs. 1004-1006, 1008-1010)**
6. The invention of claim 1, wherein the second openings are all smaller than 5 mm in minimum dimension.	Tsugita (Ex. 1003) at 8:59-61 ("*[a]n appropriate mesh is selected, having a pore size[d] [to] . . . capturing therein undesired particles of a targeted size*."), 9:5-8; Bates III (Ex. 1007) at 8:59-60 ("*[o]nce fragmented, the pieces of the stone can be about 2 mm to 10 mm in diameter*"). Wagoner Decl. (Ex. 1028) at ¶¶ 131-137.
7. The invention of claim 1, wherein movement of the sheath movement element in the first direction causes the basket to completely collapse inside the lumen of the sheath.	Leslie (Ex. 1004) at 6:4-10, Figs. 1 and 4; 6:4-9 ("*[a]s the slider 14 advances to a distal position 14B as depicted in phantom [in Fig. 1], the sheath 17 advances . . . [and] compacts and covers the retrieval basket 15 within a central aperture of the sheath*"); Bates I (Ex. 1005) at 3:36-50, 4:26-38, 6:5-10, 6:27-35, Fig. 3; Wagoner Decl. (Ex. 1028) at ¶¶ 138-144.
8. The invention of claim 1, wherein the sheath movement element comprises a slide, wherein the handle comprises a grip, and wherein the slide is mounted for translation relative to the grip.	Leslie (Ex. 1004) at Fig. 1, 5:60-66 ("*[t]he surgical extractor 10 includes a handle 11 at a proximal end 12 having a base 13 and a slider 14. A physician can grasp the base 13 in the palm in his or her hand and manipulate the slider 14 with his or her thumb*"); Bates I (Ex. 1005) at 3:36-50, 4:26-38, 6:5-10, Figs. 7 and 8; Wagoner Decl. (Ex. 1028) at ¶¶ 145-151.

B. Ground 2: Claims 1-8 are Obvious over Leslie in View of Tsugita, Bates II or Bates IV

The combination of Leslie with any of Tsugita, Bates II or Bates IV discloses each and every element of Claims 1-8.

1. Claim 1

As discussed above, Leslie discloses each of the limitations of Claim 1 of the '327 Patent except for a basket comprised of a "set of longitudinal basket

filaments radiating from the first end portion of the support filament and a set of lateral basket filaments extending between the longitudinal basket filaments," with the lateral filaments positioned primarily in the stone-retention region. Ex. 1001 at 6:40-45. Wagoner Decl. (Ex. 1028) at ¶¶ 80, 152, 157.

a. Baskets with Lateral and Longitudinal Filaments Were a Familiar Element of the Prior Art

The prior art in 2001 disclosed several examples of baskets with lateral and longitudinal filaments in their stone retention regions, including Tsugita, Bates II and Bates IV:

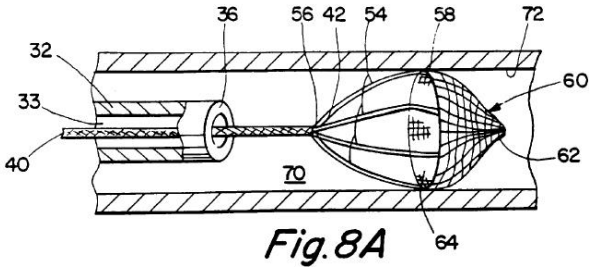


Fig. 8A

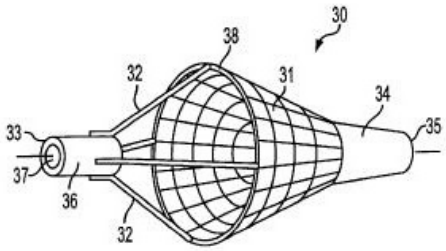


FIG. 2A

Tsugita (Ex. 1003) at 7:57-8:5, Figs. 3 and 8A; Bates IV (Ex. 1013) at Fig. 2A; *see also* Bates II (Ex. 1006) at Fig. 6. In light of this prior art, a basket with lateral and longitudinal filaments could not provide a patentable distinction between the claimed invention and the prior art. Wagoner Decl. (Ex. 1028) at ¶¶ 80, 175.

b. Motivation to Combine

A person having ordinary skill in the art in 2001 would have had both general and specific motivations to combine Leslie with any of Tsugita, Bates II or Bates IV. Wagoner Decl. (Ex. 1028) at ¶¶ 177-181. On a general level, one of

ordinary skill in the art would have been motivated to combine Leslie with any reference disclosing a retrieval basket used to remove objects from body passageways. Wagoner Decl. (Ex. 1028) at ¶¶ 177-181. For example, Hawkins (Ex. 1015) is directed to a surgical device for the removal of "objects, particularly blood clots, gallstones and kidney stones, purulent material and arthroma" from a "body passageway or cavity." Ex. 1015 at 3:9-16; Wagoner Decl. (Ex. 1028) at ¶¶ 177-181. As noted earlier, and explained by Dr. Wagoner, prior art patents routinely (1) disclosed devices with baskets used to remove objects from *both* blood vessels *and* the urinary tract system, or (2) cited to prior art in both areas. *See, e.g.*, Hawkins (Ex. 1015) at 3:9-16 and Fig. 1; Tran (Ex. 1023) at 1:7-13 and Figs. 3C and 4C; Wagoner Decl. (Ex. 1028) at ¶¶ 177-181.

On a more specific level, one of ordinary skill in the art would have been motivated to combine Leslie with any of Tsugita, Bates II or Bates IV to solve the problem of entrapping smaller-sized stones and preventing them from becoming dislodged from the basket. Wagoner Decl. (Ex. 1028) at ¶¶ 177-181. This problem became especially acute at least as early as the 1990s due to the increased use of lithotripsy, in which physicians used ultrasound shock waves to break stones into smaller fragments. *Id.* at ¶¶ 177-181.

To capture and retain such stones, skilled artisans recognized at least as early as the 1990s that an increase in the number of filaments in the distal end of a

retrieval basket would result in "closer spacing" between the filaments. *Id.* at ¶¶ 177-181; Leslie (Ex. 1004) at 7:20-27, 11:3-18. This, in turn, would allow for the "retention" of smaller stones that could not be captured by the wider spacing created by fewer filaments. *Id.*

One way to achieve such "closer spacing" would be to deploy lateral and longitudinal filaments in the distal end of the basket to form a "net" with sufficiently small openings or "pore sizes." Wagoner Decl. (Ex. 1028) at ¶¶ 177-181; *see also* Tsugita (Ex. 1003) at 8:59-61 (the "pore size" could be sufficiently small to capture "particles of a targeted size"); Bates III (Ex. 1007) at 3:32-35 (a "tight mesh" will not "allow any substantial particulate" to get through). This advantage provided a powerful motivation to combine Leslie with any of Tsugita, Bates II or Bates IV by using lateral and longitudinal filaments in the distal end of the parachute-style basket. *Id.*

Accordingly, the combination of Leslie with any of Tsugita, Bates II or Bates IV renders Claim 1 obvious. Wagoner Decl. (Ex. 1028) at ¶¶ 80, 152.

2. Claim 2

Claim 2 requires the stone-retention region to define an internally concave surface facing the first end portion of the support filament. Leslie discloses such an internally concave surface, as shown in Figure 8 below. *See*, *e.g.*, Ex. 1004 at Fig. 8; *see also* Wagoner Decl. (Ex. 1028) at ¶¶ 183-185.

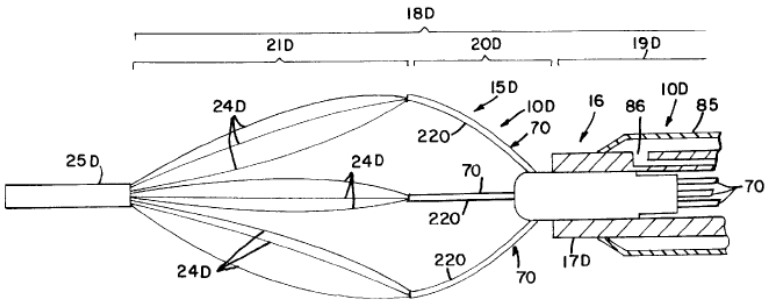


FIG. 8

3. Claims 3, 4 and 6

Claims 3 and 6 recite that the openings of the stone-retention region are smaller than 2 mm and 5 mm respectively. Claim 4 recites that the size of the first opening of the stone-entrance region is larger than 2 mm. It was well known in 2001 that the diameter of fragmented kidney stones ranged from 2-10 mm. Bates III (Ex. 1007) at 8:59-60. It was also well known that the openings in a basket or filter could be designed to capture "particles of a targeted size." Tsugita (Ex. 1003) at 8:59-61; Bates III (Ex. 1007) at 8:59-65; Wagoner Decl. (Ex. 1028) at ¶¶ 186-193.

Accordingly, as the Examiner noted during prosecution, "it would have been an obvious matter of dimensioning to one of ordinary skill in art to produce a web or mesh having holes sized within the range claimed." Ex. 1002 at 55-56, 91. Indeed, at his deposition, the inventor conceded that the specific dimensions used in Claims 3, 4 and 6 were "*arbitrary numbers that I picked*," and not based on any "scientific study." Ex. 1011 at 191-92; Wagoner Decl. (Ex. 1028) at ¶¶ 186-193.

4. Claims 5 and 7

Dependent Claim 5 adds the limitation that the sheath and support filament are not attached to the retrieval basket such that the entire basket can be "collapsed" into the sheath. As discussed above, Leslie discloses a retrieval basket that is not attached to the sheath or filament and that can be collapsed in its entirety with the sheath:

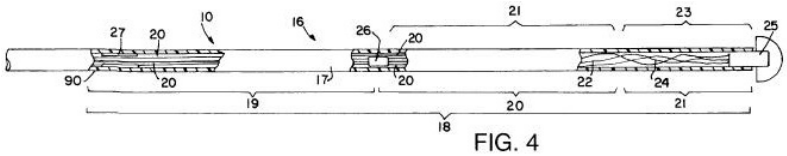


FIG. 4

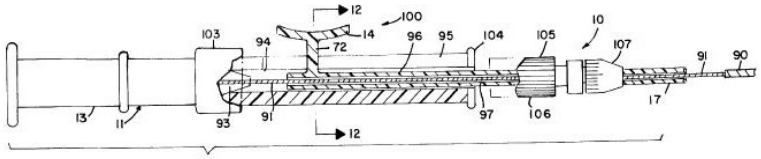
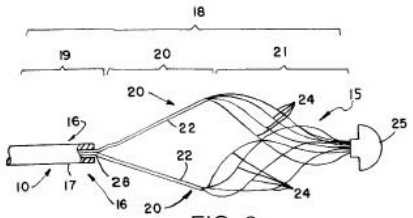
Leslie (Ex. 1004) at 6:4-10, Fig. 4; Wagoner Decl. (Ex. 1028) at ¶¶ 196-197.

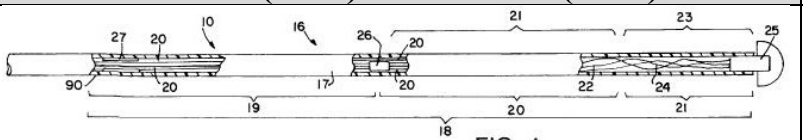
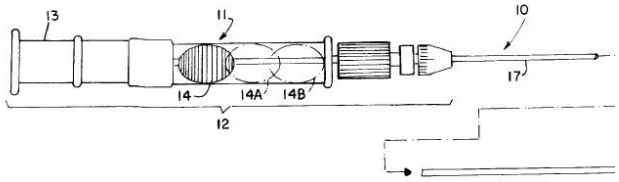
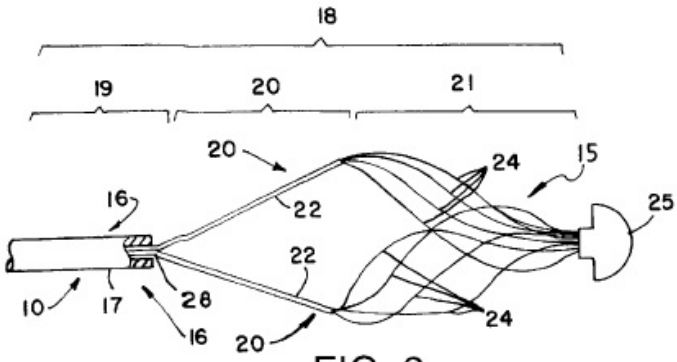
Claim 7 adds the limitation that the sheath movement element can cause the basket to collapse and fit entirely within the sheath. As shown above, Leslie discloses this limitation. Leslie (Ex. 1004) at 6:4-10; Wagoner Decl. (Ex. 1028) at ¶¶ 196, 198.

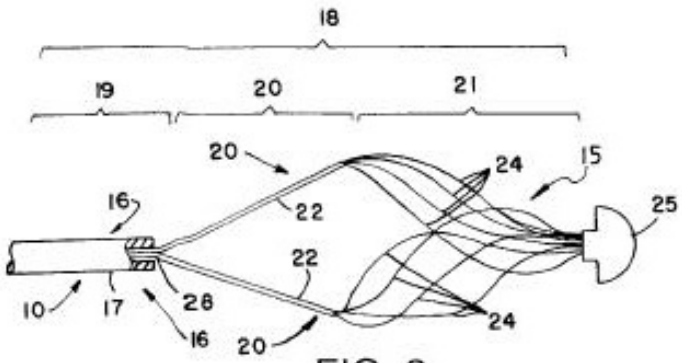
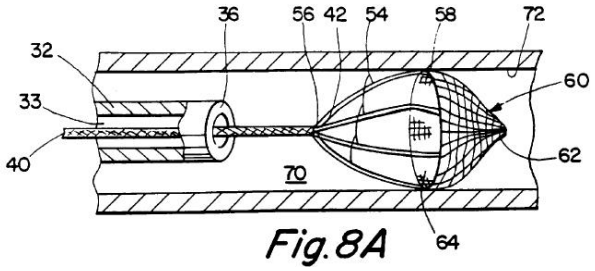
5. Claim 8

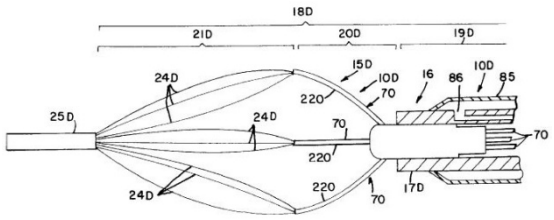
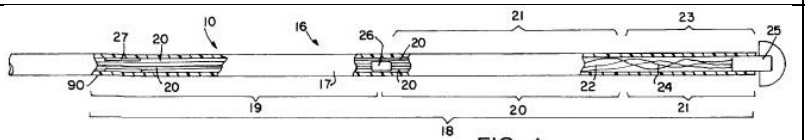
Claim 8 adds the limitation that the sheath movement element of Claim 1 also has a slide and the handle has a grip, and the slide moves relative to the grip. Leslie discloses a device that has a base (grip) (**13**) and a slider (**14**) that the physician can move back and forth in order open and close the basket. Leslie (Ex. 1004) at 4:50-54, 4:59-63, 5:7-13, 5:60-66; Wagoner Decl. (Ex. 1028) at ¶¶ 201-203.

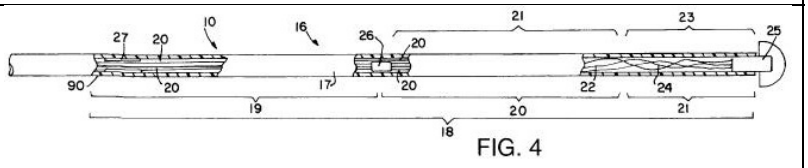
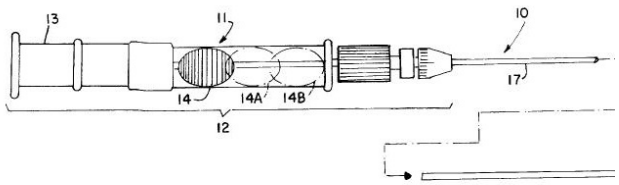
The table below demonstrates how the combination of Leslie with any of Tsugita, Bates II or Bates IV teaches each of the limitations of Claims 1-8 of the '327 Patent.

'327 Patent Claim Elements	**Leslie (Ex. 1004) in view of Tsugita (Ex. 1003), Bates II (1006) or Bates IV (1013)**
1. An endoscopic stone-extraction device comprising:	Leslie (Ex. 1004) at 1:10-13 ("*an extractor for removing . . . calculi that can form in the biliary and urinary systems*"); Wagoner Decl. (Ex. 1028) at ¶¶ 154-155, 158-160.
1A. a support filament comprising a first end portion and a second end portion;	Leslie (Ex. 1004) at 4:64-5:13 (cable 90 attaches to rod 91), 10:23-36, Figs. 4, 11; Wagoner Decl. (Ex. 1028) at ¶¶ 161-162.  FIG. 11
1B. a sheath comprising a lumen, the support filament disposed in the lumen such that the sheath is slideable with respect to the support filament;	Leslie (Ex. 1004) at Figs. 1, 4 and 11, 10:19-35, 10:60-62 ("*the slider 14 and the sheath 17 move relative to the rod 91, the cable 90 and the retrieval basket 15*"); Wagoner Decl. (Ex. 1028) at ¶ 163.
1C. a collapsible stone-extraction basket carried by the first end portion of the support filament and receivable within the lumen of the sheath;	Leslie (Ex. 1004) at 4:64-5:13, 6:4-10 ("*the sheath 17 advances from the position depicted in FIG. 2 . . .to the position illustrated in FIG. 4*")  FIG. 2

'327 Patent Claim Elements	**Leslie (Ex. 1004) in view of Tsugita (Ex. 1003), Bates II (1006) or Bates IV (1013)**
	 FIG. 4 Wagoner Decl. (Ex. 1028) at ¶ 164.
1D. a handle comprising a sheath movement element, wherein movement of the sheath movement element in a first direction advances the sheath and causes the basket to at least partially collapse inside the lumen of the sheath, and wherein movement of the sheath movement in a second direction retracts the sheath and causes the basket to expand to an operational shape outside the lumen of the sheath;	 FIG. 1 Leslie (Ex. 1004) at Figs. 1 and 4, 4:38-44, 4:59-63, 5:7-14, 6:3-10, 6:52-63 ("*the physician moves the slider 14 from position 14B to the position 14 in FIG. 1. This retracts the sheath 17 . . . of the basket assembly 18*"), 7:33-38 ("*the physician advances the sheath 17 distally and reduces the volume of the retrieval basket 15*"); Wagoner Decl. (Ex. 1028) at ¶¶ 165-169.
1E. the basket, when expanded to the operation shape outside the lumen of the sheath, comprising a stone-entrance region and a stone-retention region, the stone-entrance region comprising a first opening sized to admit a stone into the basket, the stone-retention region comprising a plurality of second openings, all of the second openings being smaller than the first opening;	 FIG. 2 Leslie (Ex. 1004) at Fig. 2, 2:48-52, 4:20-26 ("*a surgical extractor that provides a plurality of filaments in the distal portion and individual filaments in the proximal portion to optimize both the entry and capture of objects in the proximal*

'327 Patent Claim Elements	**Leslie (Ex. 1004) in view of Tsugita (Ex. 1003), Bates II (1006) or Bates IV (1013)**
	portion of the retrieval basket and retention of such objects in the distal portion of the retrieval basket") 7:4-6, 7:17-37, 11:4-8; Wagoner Decl. (Ex. 1028) at ¶¶ 170-173.
1F. the first opening facing the first end portion of the support filament, the stone-retention region positioned on a side of the basket opposite the first end portion of the support filament;	 FIG. 2 Leslie (Ex. 1004) at 2:48-52, 4:20-26, Fig. 2; Wagoner Decl. (Ex. 1028) at ¶ 174.
1G. wherein the basket comprises a set of longitudinal basket filaments radiating from the first end portion of the support filament and a set of lateral basket filaments extending between the longitudinal basket filaments, the lateral basket filaments positioned substantially entirely in the stone-retention region of the basket.	Tsugita (Ex. 1003) at 12:16-23, Fig. 8A; *see also* Bates IV (Ex. 1013) at Fig. 2A; Bates II (Ex. 1006) at Fig. 6 and 7:39-49; Leslie (Ex. 1004) at Fig. 2; Wagoner Decl. (Ex. 1028) at ¶¶ 175-176.  Fig. 8A Ex. 1003 at Fig. 8A.

'327 Patent Claim Elements	**Leslie (Ex. 1004) in view of Tsugita (Ex. 1003), Bates II (1006) or Bates IV (1013)**
2. The invention of claim 1 wherein the stone-retention region defines an internally concave surface facing the first end portion of the support filament.	 FIG. 8 Leslie (Ex. 1004) at Fig. 8; Wagoner Decl. (Ex. 1028) at ¶ 183-185.
3. The invention of claim 1 wherein the second openings are all smaller than 2 mm in minimum dimension.	Tsugita (Ex. 1003) at 8:59-61 ("*[a]n appropriate mesh is selected, having a pore size[d] [to] . . . capturing therein undesired particles of a targeted size*."); Bates III (Ex. 1007) at 8:59-60 ("*[o]nce fragmented, the pieces of the stone can be about 2 mm to 10 mm in diameter*"). Wagoner Decl. (Ex. 1028) at ¶¶186-193.
4. The invention of claim 3 wherein the first opening is larger than 2 mm in minimum dimension.	Tsugita (Ex. 1003) at 8:59-61 ("*[a]n appropriate mesh is selected, having a pore size[d] [to] . . . capturing therein undesired particles of a targeted size*."), 9:5-8; Bates III (Ex. 1007) at 8:59-60 ("*[o]nce fragmented, the pieces of the stone can be about 2 mm to 10 mm in diameter*"); Wagoner Decl. (Ex. 1028) at ¶¶ 186-193.
5. The invention of claim 1 wherein the support filament and basket are free of attachment to the sheath, such that the entire basket is movable into the lumen of the sheath.	 FIG. 4 Leslie (Ex. 1004) at Fig. 4 ("*[i]n FIG. 4 the sheath 17 compacts and covers the retrieval basket 15 within a central aperture of the sheath*"), 6:4-10; Wagoner Decl. (Ex. 1028) at ¶¶ 194-199.
6. The invention of claim 1, wherein the second openings are all smaller than 5 mm in minimum	Tsugita (Ex. 1003) at 8:59-61 ("*[a]n appropriate mesh is selected, having a pore size[d] [to] . . . capturing therein undesired particles of a targeted size*."), 9:5-8; Bates III (Ex. 1007) at 8:59-60 ("*[o]nce fragmented, the pieces of the stone can be*

'327 Patent Claim Elements	**Leslie (Ex. 1004) in view of Tsugita (Ex. 1003), Bates II (1006) or Bates IV (1013)**
dimension.	*about 2 mm to 10 mm in diameter*"). Wagoner Decl. (Ex. 1028) at ¶¶ 186-193.
7. The invention of claim 1, wherein movement of the sheath movement element in the first direction causes the basket to completely collapse inside the lumen of the sheath.	 FIG. 4 Leslie (Ex. 1004) at 6:4-9 ("*[a]s the slider 14 advances to a distal position 14B as depicted in phantom [in Fig. 1], the sheath 17 advances . . . [and] compacts and covers the retrieval basket 15 within a central aperture of the sheath*"), 6:52-63, Fig. 4; Wagoner Decl. (Ex. 1028) at ¶¶ 194-199.
8. The invention of claim 1, wherein the sheath movement element comprises a slide, wherein the handle comprises a grip, and wherein the slide is mounted for translation relative to the grip.	Leslie (Ex. 1004) at Fig. 1 and 4:50-54, 4:59-63; 5:7-13, 5:60-66 ("*[t]he surgical extractor 10 includes a handle 11 . . . having a base 13 and a slider 14. A physician can grasp the base 13 . . . and manipulate the slider 14 with his or her thumb*"), 6:53-67, 10:59-67; Wagoner Decl. (Ex. 1028) at ¶¶ 200-203.  FIG. 1

C. Ground 3: Claims 1-8 are Obvious Over the Combination of Bates I and Either of Tsugita or Bates IV

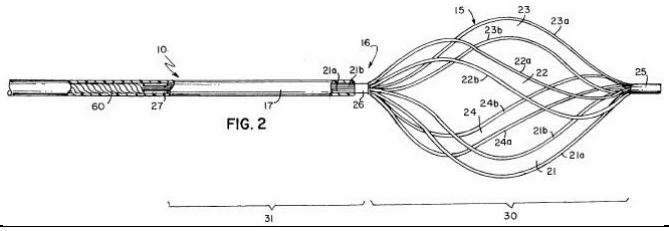
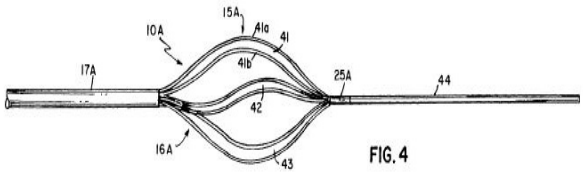
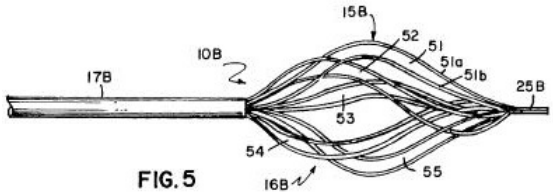
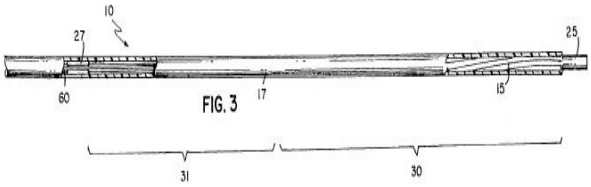
The combination of Bates I with either of Tsugita or Bates IV renders obvious Claims 1-8. Wagoner Decl. (Ex. 1028) at ¶¶ 80, 204. As shown above, Bates I discloses all of the material limitations of the claimed invention except for the deployment of lateral and longitudinal filaments as part of a stone retention

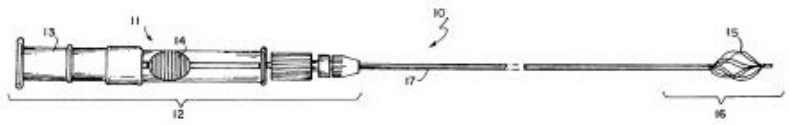
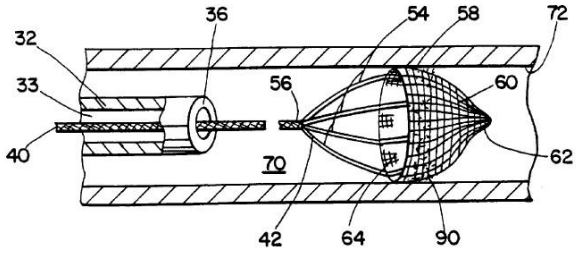
region in the distal part of a parachute-style retrieval basket. Wagoner Decl. (Ex. 1028) at ¶¶ 204-206, 208. Such a configuration was already well-known in the prior art. *See, e.g.,* Tsugita (Ex. 1003) at 12:16-23, Fig. 8A; Bates IV (Ex. 1013) at Fig. 2A; Wagoner Decl. (Ex. 1028) at ¶¶ 61-68. Accordingly, this distinction does not provide a patentable difference in the case of Bates I any more than it does in the case of Leslie. Wagoner Decl. (Ex. 1028) at ¶¶ 80, 217-223.

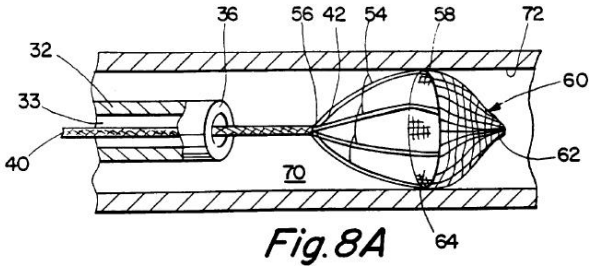
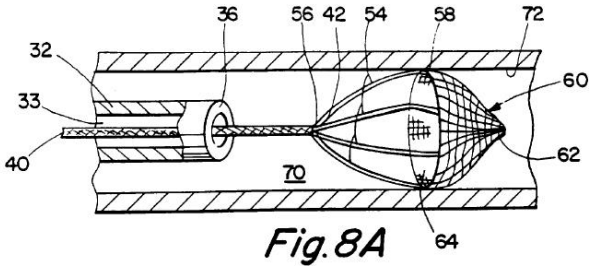
Furthermore, a person of ordinary skill in the art in 2001 would have had the same general and specific motivations to combine Bates I with either Tsugita or Bates IV that he had to combine Leslie with the same references. Wagoner Decl. (Ex. 1028) at ¶¶ 177-181, 224. These motivations include the recognition that the use of a parachute-style retrieval basket with a greater number of filaments in its distal end would result in "closer spacing" between the filaments and thus create a "netting effect" that would facilitate the capture and retention of stones. Wagoner Decl. (Ex. 1028) at ¶¶ 177-181, 224.

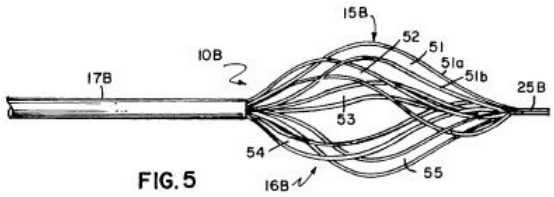
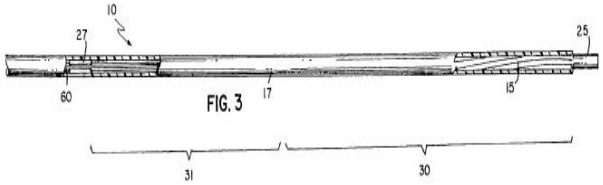
Accordingly, the table below demonstrates that the combination of Bates I with either of Tsugita or Bates IV teaches each of the limitations of Claims 1-8 of the '327 Patent:

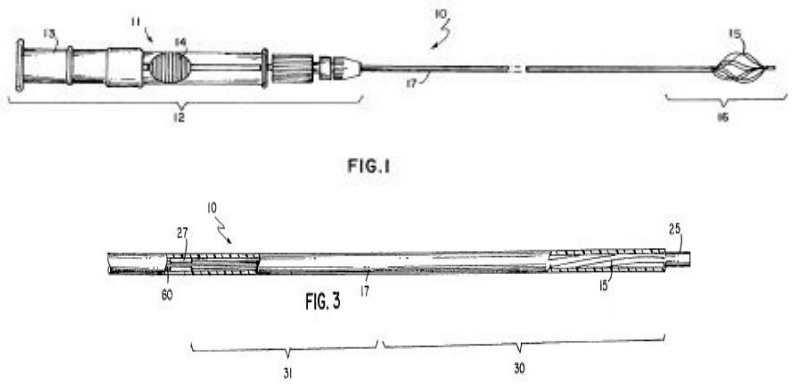
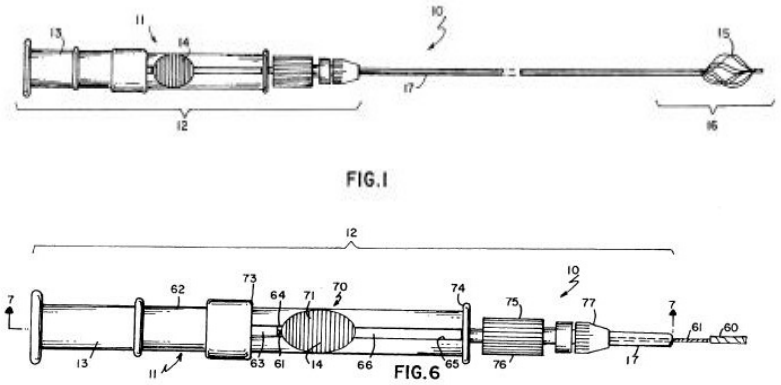
'327 Patent Claim Elements	**Bates I (Ex. 1005) in View of Tsugita (Ex. 1003) or Bates IV (Ex. 1013)**
1. An endoscopic stone-extraction device comprising:	Bates I (Ex. 1005) at 1:11-14, 3:36-45, Abstract ("*[a] surgical extractor for removing calculi*"); Wagoner Decl. (Ex. 1028) at ¶¶ 206, 209.

'327 Patent Claim Elements	**Bates I (Ex. 1005) in View of Tsugita (Ex. 1003) or Bates IV (Ex. 1013)**
1A. a support filament comprising a first end portion and a second end portion;	Bates I (Ex. 1005) at 5:57-65, Figs. 2, 3, 6 and 7; Wagoner Decl. (Ex. 1028) at ¶ 210.  FIG. 2
1B. a sheath comprising a lumen, the support filament disposed in the lumen such that the sheath is slideable with respect to the support filament;	Bates I (Ex. 1005) at 3:43-51, 4:26-38, Figs. 2, 3, 6 and 7, 6:28-31 ("*the sheath 17 move[s] relative to the rod 61, the cable 60 and the retrieval basket*"); Wagoner Decl. (Ex. 1028) at ¶ 211.
1C. a collapsible stone-extraction basket carried by the first end portion of the support filament and receivable within the lumen of the sheath;	 FIG. 4  FIG. 5  FIG. 3 Bates I (Ex. 1005) at 1:32-38, 3:41-49, 5:62-65, Figs. 2-5, 3:47-50 ("*the sheath 17 advances to compact and cover the retrieval basket 15 as shown in FIG. 3*"); Wagoner Decl. (Ex. 1028) at ¶ 212.

'327 Patent Claim Elements	**Bates I (Ex. 1005) in View of Tsugita (Ex. 1003) or Bates IV (Ex. 1013)**
1D. a handle comprising a sheath movement element, wherein movement of the sheath movement element in a first direction advances the sheath and causes the basket to at least partially collapse inside the lumen of the sheath, and wherein movement of the sheath movement element in a second direction retracts the sheath and causes the basket to expand to an operational shape outside the lumen of the sheath;	 FIG.I Bates I (Ex. 1005) at Abstract, Figs. 2, 3, 6 and 7, 3:36-50 ("*[w]hen the slider 14 advances to a distal position, that is to the right in FIGS. 1 and 2, the sheath 17 advances to compact and cover the retrieval basket 15 as shown in FIG. 3*"), 4:22-37 ("*the physician uses the slider 14 [to the left] in FIG. 1 to retract the sheath 17 and expose the wires [of the basket]*"); Wagoner Decl. (Ex. 1028) at ¶¶ 213-216.
1E. the basket, when expanded to the operation shape outside the lumen of the sheath, comprising a stone-entrance region and a stone-retention region, the stone-entrance region comprising a first opening sized to admit a stone into the basket, the stone-retention region comprising a plurality of second openings, all of the second openings being smaller than the first opening;	Tsugita (Ex. 1003) at 3:57-63, Figs 8A and 8B; Wagoner Decl. (Ex. 1028) at ¶¶ 217-220.  Fig. 8B *See also* Bates IV (Ex. 1013) at Fig. 2A.
1F. the first opening facing the first end portion of the support filament, the stone-retention region	Tsugita (Ex. 1003) at Figs. 8A and 8B.

'327 Patent Claim Elements	**Bates I (Ex. 1005) in View of Tsugita (Ex. 1003) or Bates IV (Ex. 1013)**
positioned on a side of the basket opposite the first end portion of the support filament;	 Fig. 8A *See also* Bates IV (Ex. 1013) at Fig. 2A; Wagoner Decl. (Ex. 1028) at ¶¶ 221-222.
1G. wherein the basket comprises a set of longitudinal basket filaments radiating from the first end portion of the support filament and a set of lateral basket filaments extending between the longitudinal basket filaments, the lateral basket filaments positioned substantially entirely in the stone-retention region of the basket.	Tsugita (Ex. 1003) at 12:16-23, Fig. 8A, 8B; Wagoner Decl. (Ex. 1028) at ¶ 223.  Fig. 8A *See also* Bates IV (Ex. 1013) at Fig. 2A.
2. The invention of claim 1 wherein the stone-retention region defines an internally concave surface facing the first end portion of the support filament.	Tsugita (Ex. 1003) at Figs 8A and 8B; *see also* Bates IV (Ex. 1013) at Fig. 2A; Wagoner Decl. (Ex. 1028) at ¶¶ 225-228.
3. The invention of claim 1 wherein the second openings are all smaller than 2 mm in minimum dimension.	Tsugita (Ex. 1003) at 8:59-61 ("*[a]n appropriate mesh is selected, having a pore size[d] [to] . . . capturing therein undesired particles of a targeted size*."); Bates III (Ex. 1007) at 8:59-60 ("*[o]nce fragmented, the pieces of the stone can be about 2 mm to 10 mm in diameter*"); Wagoner Decl. (Ex. 1028) at

'327 Patent Claim Elements	**Bates I (Ex. 1005) in View of Tsugita (Ex. 1003) or Bates IV (Ex. 1013)**
	¶¶ 229-234.
4. The invention of claim 3 wherein the first opening is larger than 2 mm in minimum dimension.	Tsugita (Ex. 1003) at 8:59-61 ("*[a]n appropriate mesh is selected, having a pore size[d] [to] . . . capturing therein undesired particles of a targeted size*.") 9:5-8; Bates III (Ex. 1007) at 8:59-60 ("*[o]nce fragmented, the pieces of the stone can be about 2 mm to 10 mm in diameter*"); Wagoner Decl. (Ex. 1028) at ¶¶229-234.
5. The invention of claim 1 wherein the support filament and basket are free of attachment to the sheath, such that the entire basket is movable into the lumen of the sheath.	 FIG. 5  FIG. 3 Bates I (Ex. 1005) at 1:32-38, 3:41-45, 5:62-65, Figs. 3, 4 and 5, 3:48-50 ("*the sheath 17 advances to compact and cover the retrieval basket 15 as shown in FIG. 3*"); Wagoner Decl. (Ex. 1025) at ¶¶ 235-239.
6. The invention of claim 1, wherein the second openings are all smaller than 5 mm in minimum dimension.	Tsugita (Ex. 1003) at 8:59-61 ("*[a]n appropriate mesh is selected, having a pore size[d] [to] . . . capturing therein undesired particles of a targeted size*."), 9:5-8; Bates III (Ex. 1007) at 8:59-60 ("*[o]nce fragmented, the pieces of the stone can be about 2 mm to 10 mm in diameter*"); Wagoner Decl. (Ex. 1028) at ¶¶ 229-234.

'327 Patent Claim Elements	**Bates I (Ex. 1005) in View of Tsugita (Ex. 1003) or Bates IV (Ex. 1013)**
7. The invention of claim 1, wherein movement of the sheath movement element in the first direction causes the basket to completely collapse inside the lumen of the sheath.	 Bates I (Ex. 1005) at 3:36-50, 4:26-38, 6:5-10, 6:27-35, Figs. 1, 3; 3:48-51("*[w]hen the slider 14 advances to a distal position, that is to the right in FIGS. 1 and 2, the sheath 17 advances to compact and cover the retrieval basket 15 as shown in FIG. 3*"); Wagoner Decl. (Ex. 1028) at ¶¶ 235-239.
8. The invention of claim 1, wherein the sheath movement element comprises a slide, wherein the handle comprises a grip, and wherein the slide is mounted for translation relative to the grip.	 Bates I (Ex. 1005) at 3:36-50, 4:26-38, 6:5-10, Figs. 1 and 6; 3:37-41 ("*[t]he surgical extractor 10 includes a handle 11 at a proximal end 12 having a base 13 and a slider 14. A physician can grasp the base 13 in the palm of his or her hand and manipulate the slider 14 with his or her thumb*"); Wagoner Decl. (Ex. 1028) at ¶¶ 240-243.

IX. CONCLUSION

The references above show that Petitioner is likely to prevail in showing that the alleged inventions in the challenged claims of the ’327 Patent are invalid under 35 U.S.C. § 103. Accordingly, the Petitioner respectfully requests that the Board grant this petition for *inter partes* review and find that Claims 1-8 of the ’327 Patent are unpatentable.

Dated: March 4, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on March 4, 2016, a copy of the attached PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,551,327, together with all exhibits, the power of attorney, and all other papers filed therewith was served by UPS on the attorneys of record for the Patent Owner at the following address:

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