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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 11/327,795 | 01/06/2006 | Christopher T. Boyle | 6006-200 | 3096 |

29335 7590 01/22/2013
ROSENBAUM IP
1480 TECHNY ROAD
NORTHBROOK, IL 60062

| EXAMINER |
|---|
| MILLER, CHERYL L |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3738 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 01/22/2013 | ELECTRONIC |

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* CHRISTOPHER T. BOYLE, STEVEN R. BAILEY,
JULIO C. PALMAZ, and CHRISTOPHER E. BANAS

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Appeal 2011-005576
Application 11/327,795
Technology Center 3700

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Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims directed to an endoluminal stent. The claims have been rejected on the grounds of anticipation, obviousness and indefiniteness. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse the anticipation and obviousness rejections, and affirm the indefiniteness rejection.

## STATEMENT OF THE CASE

Claims 1-11 and 14-18 are pending and on appeal. Claims 12, 13, and 19-20 are also pending, but have been withdrawn from consideration.

Claims 1 and 18 are representative:

1. An intraluminal device comprising a generally tubular member having a plurality of struts and a plurality of interconnecting members, forming circumferential walls thereof, each of the plurality of struts further having a generally sinusoidal curve thereto defining peaks and valleys of each of the plurality of struts and arranged generally sinusoidal and parallel to a longitudinal axis of the generally tubular member, each of the plurality of struts being in spaced-apart, in-phase relationship with respect to an adjacent one of the plurality of struts substantially about a circumferential aspect of the tubular member and the plurality of interconnecting members interconnecting adjacent pairs of struts and extending between a peak of a first strut and a valley of a second strut, wherein no more than one interconnecting member connects to any given peak or valley.

18. An intraluminal stent comprising a generally tubular member having a plurality of generally sinusoidal members being substantially parallel to a longitudinal axis of the generally tubular member and extending along the entire length of the longitudinal axis, each of the plurality of generally sinusoidal members being in spaced-apart, in-phase relationship with respect to an adjacent one of the plurality of generally sinusoidal members substantially about a circumferential aspect of the tubular member; and a plurality of interconnecting members interconnecting adjacent pairs of first structural elements and extending between a peak of a first generally sinusoidal member and a valley of a second, circumferentially adjacent generally sinusoidal member, such that no more than one interconnecting member connects to any given peak or valley of adjacent generally sinusoidal members.

The Examiner relies on the following evidence:

| | | |
|---|---|---|
| Kanesaka et al. | US 5,810,872 | Sep. 22, 1998 |
| Smith et al. | US 6,409,754 B1 | Jun. 25, 2002 |
| Roubin at el. | US 6,475,236 B1 | Nov. 5, 2002 |
| Whitcher et al. | US 2003/0018381 A1 | Jan 23, 2003 |

The claims stand rejected as follows:

I. Claims 1-4 and 14-18 under 35 U.S.C. § 102(b), as anticipated by Kanesaka;

II. Claims 1-4, 8, and 18 under 35 U.S.C. § 102(e) as anticipated by Roubin.

III. Claims 5-7 and 9-11 under 35 U.S.C. § 103(a) as unpatentable over Kanesaka or Roubin, in view of Smith.

IV. Claims 7 and 9-11 under 35 U.S.C. § 103(a) as unpatentable over Kanesaka or Roubin, in view of Whitcher.

V. Claims 14-17 under 35 U.S.C. § 112, second paragraph, as indefinite.

## ANTICIPATION BY KANESAKA

### *Issue*

Independent claims 1 and 18 require, in relevant part, a generally tubular intraluminal device with a plurality of spaced apart, sinusoidal struts defining peaks and valleys, wherein the struts are parallel to the longitudinal axis of the device, and wherein adjacent struts are arranged in an "in-phase relationship" with each other "substantially about a circumferential aspect" of the device.

The Examiner finds that Kanesaka discloses a stent that meets all the limitations of independent claims 1 and 18. In particular, the Examiner finds that the stent depicted in Figure 8 of Kanesaka (reproduced below) has a plurality of sinusoidal struts parallel to the longitudinal axis of the stent, with adjacent struts in an in-phase relationship, with "peaks aligned and valleys aligned . . . about a circumferential aspect of the tubular member" (Ans. 6). That is, the Examiner finds that the peaks and valleys of adjacent struts on

Kanesaka's stent are aligned along a helical line that extends around the circumference of Kanesaka's stent, and "[a] helical line . . . [that] extends around the circumference . . . may be considered a circumferential aspect as much as a circular perpendicular line" (*id.* at 10).

Appellants contend that Kanesaka's struts are not in an "in-phase relationship with respect to an adjacent one of the plurality of struts substantially about a circumferential aspect of the tubular member" as required by the claims on appeal, when the claims are interpreted in light of the Specification (App. Br. 12).

The issue raised by this rejection is whether the Examiner has established that adjacent struts in Kanesaka's device are arranged in an "in-phase relationship . . . substantially about a circumferential aspect" of the device as required by the claims on appeal, when the claims are interpreted in light of the Specification.

*Findings of Fact*

1. Figure 1 of the present Specification is reproduced below:

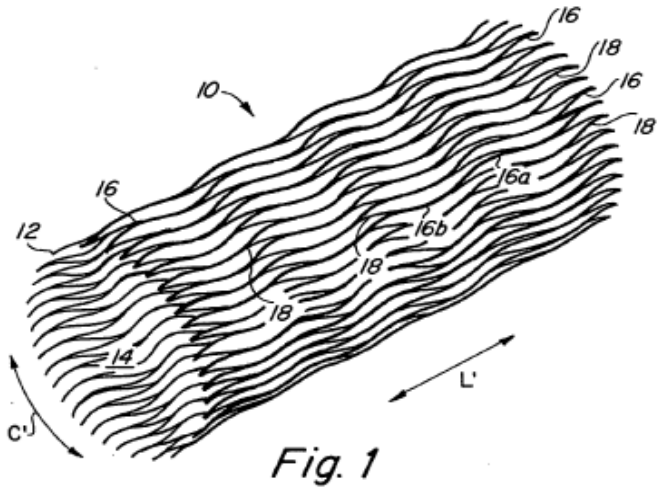



Fig. 1

Figure 1 of the Specification is a perspective view of a stent 10 that meets the limitations of independent claims 1 and 18. Stent 10 "consists

generally of a tubular cylindrical element . . . A plurality of first structural elements 16 are arrayed about the circumferential axis C= [sic, C'] of the stent 10 and extend parallel along the longitudinal axis of stent 10" (Spec. 10: 6-8). The "first structural elements 16 have a generally sinusoidal configuration with a plurality of peaks 16a and a plurality of troughs 16b" (*id.* at 10: 10-11), and "[a] plurality of second structural elements 18 interconnects adjacent pairs of the . . . first structural elements 16" (*id.* at 10: 8-9).

2. Figures 2A and 2B of the present Specification are reproduced below:

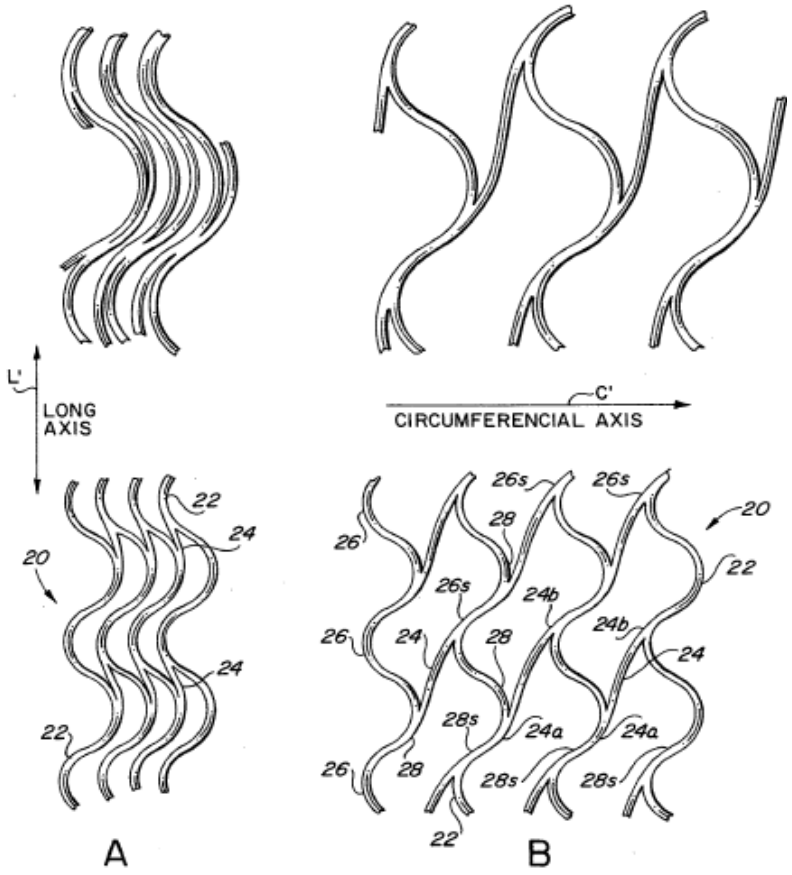



Fig. 2

Figures 2A and 2B of the Specification depict compressed and expanded fragmentary side elevational views of a stent 20 that meets the limitations of claims 1 and 18. Stent 20 "consists of a plurality of first structural elements 22 and a plurality of second structural elements 24 which interconnect adjacent pairs of the . . . first structural elements 22" (Spec. 15: 27-30). The first structural elements 22 "extend[] parallel to the longitudinal axis L= [sic, L'] of the stent 20 . . . [and] ha[ve] a sinusoidal configuration consisting of a plurality of successive peaks 26 and troughs 28" (*id.* at 15: 30 - 16: 4).

The "first structural elements 22 are arrayed about the circumference of stent 20 such that the peaks 26 and the troughs 28 of each individual first structural element 22 are in phase with respect to adjacent peaks 26 and troughs 28 of adjacent first structural elements 22" (*id.* at 16: 4-7).

3. Figure 8 of Kanesaka is reproduced below:

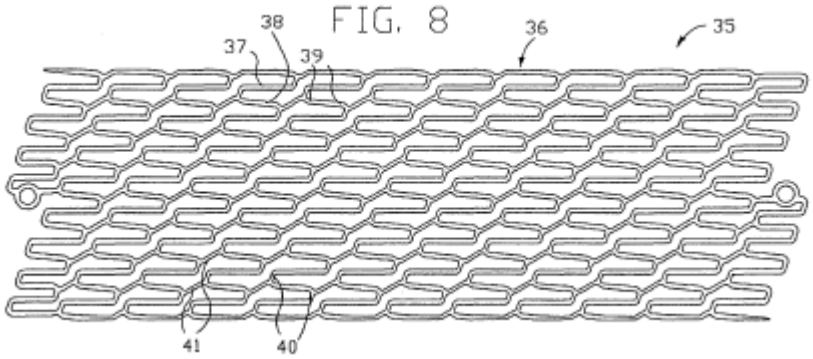



Figure 8 of Kanesaka depicts stent 35, "formed of a plurality of tortuous members **36** spirally arranged in a cylindrical form" (Kanesaka, col. 5, ll. 16-17). "The tortuous member **36** includes long struts **37**, and short struts **38** . . . Connecting portions **40** connect the short and long struts **37**, **38** to form the tortuous member **36**. The tortuous members **36** situated adjacent to each other are connected by joint struts **41**" (*id.* at col. 5, ll. 17-22).

*Discussion*

According to the Examiner, Kanesaka's stent has sinusoidal struts, made up of elements 38 and 41, which extend along the longitudinal axis of the stent, and are interconnected by elements 37. The Examiner further finds that the peaks and valleys of adjacent struts on Kanesaka's stent are aligned, i.e., are in phase, along a circumferential aspect of the stent (Ans. 6), since "[a] helical line still extends around the circumference and may be considered a circumferential aspect as much as a circular perpendicular line" (*id.* at 10).

The Specification does not explicitly define the term "in-phase . . . about a circumferential aspect," but it does provide numerous examples of sinusoidal struts arranged in such a manner. In Figures 2A and 2B, and in every other figure describing an "in phase" embodiment, the peaks and troughs (or valleys) of adjacent sinusoidal struts are aligned along a circumferential axis perpendicular to the longitudinal axis of the device (FF2; *see also* Figures 3-5; Spec. 17: 3-6, 18: 2-5, 29-30; 19: 1-2). No embodiment described in the Specification has the peaks and valleys of adjacent sinusoidal struts aligned along a helical line.

We agree with Appellants that the Examiner has not established that adjacent struts in Kanesaka's device, which are aligned along an imaginary line spiraling around the stent, are arranged in an "in-phase relationship . . . about a circumferential aspect" of the device as required by the claims on appeal, when the claims are interpreted in light of the Specification (App. Br. 12; Reply Br. 6).

The rejection of claims 1-4 and 14-18 as anticipated by Kanesaka is reversed.

ANTICIAPTION BY ROUBIN

*Issue*

Independent claim 1 also requires, in relevant part, "interconnecting members interconnecting adjacent pairs of struts and extending between a peak of a first strut and a valley of a second strut." Claim 18 has a similar requirement.

The Examiner finds that Roubin discloses a stent that meets all the limitations of independent claims 1 and 18. In particular, the Examiner finds that the stent depicted in Figure 4A of Roubin (reproduced below) has a plurality of struts "being generally sinusoidal and parallel to a longitudinal axis of the [stent]" (Ans. 7), wherein "interconnecting members . . . extend[] between a peak of a first strut and a valley of a second strut" (*id.*).

Appellants contend that the claims require "interconnecting members interconnecting adjacent pairs of struts and extending between a peak of a first strut and a valley of a second strut where the struts extend . . . generally parallel to a longitudinal axis" of the stent, while Roubin's stent, in contrast, is "comprised of annular elements connected by longitudinal connecting members" (App. Br. 14-15). Moreover, Appellants contend that Roubin "does not disclose a 'plurality of interconnecting members interconnecting adjacent pairs of struts and extending between a peak of a first strut and a valley of a second strut," as required by the claims on appeal (*id.* at 17-18).

The issue raised by this rejection is whether the Examiner has established that Roubin discloses a stent with longitudinal, sinusoidal struts with "interconnecting members interconnecting adjacent pairs of struts and extending between a peak of a first strut and a valley of a second strut" as required by the claims on appeal.

*Findings of Fact*

4. Figure 4A of Roubin is reproduced below:

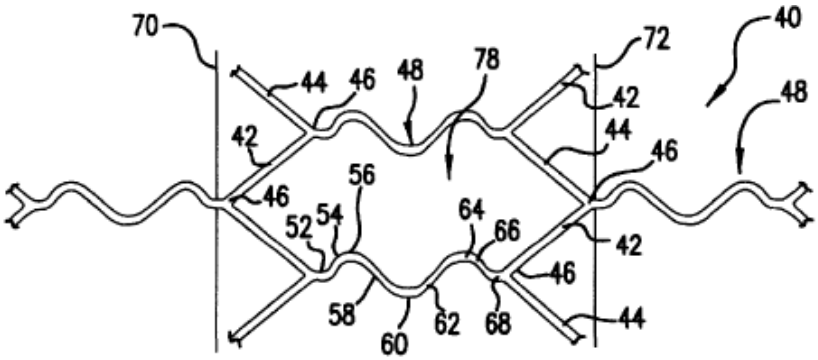


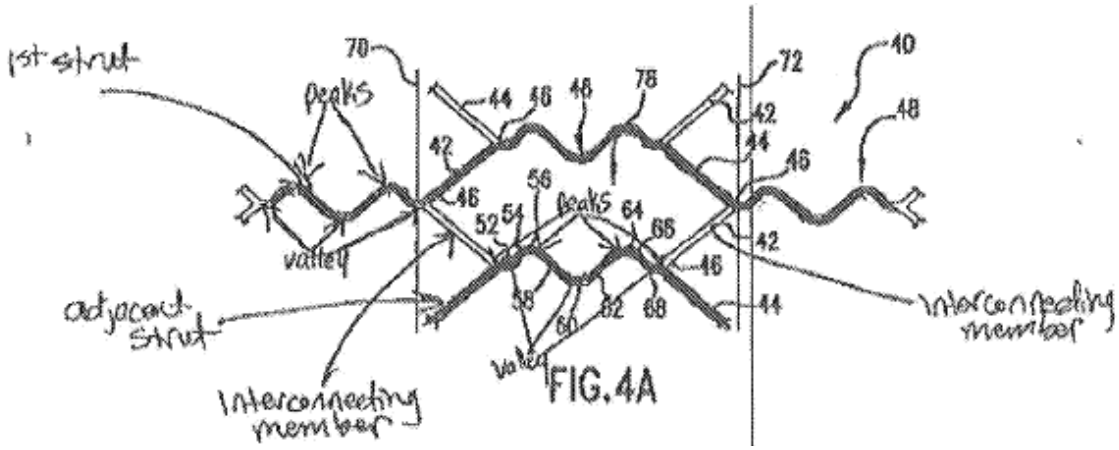

FIG.4A

Figure 4A is a side elevational view of Roubin's stent with the longitudinal axis of the stent extending between the left and right sides of the figure. Roubin teaches that "[t]he stent **40** has a plurality of pairs of alternating left struts **42** and right struts **44**. Each pair of left and right struts **42**, **44** is connected at an apex **46** to form a substantially V-shape for the pair" (Roubin, col. 5, ll. 40-43). "[T]he alternating left and right struts **42** and **44** extend in an annular manner around the tubular stent **40** to form an annular element" and "[e]ach apex **46** is connected to another apex **46** by a connecting member **48**" (*id.* at col. 5, ll. 50-53). "Each connecting member **48** extends longitudinally along a longitudinal extension **52** from an apex **46** . . . [and] has a plurality of alternating curved segments that are defined by the alternating top and bottom apices **56**, **60** and **64**" (*id.* at col. 5, l. 65 - col. 6, l. 11).

5. Roubin teaches that the stent can be "fabricated from a solid Nitinol tube . . . [by] a computer-guided laser cutter or lathe which cuts out the segments between the struts **42**, **44** and the connecting members **48**" (Roubin, col. 9, ll. 27-33).

*Discussion*

Roubin's stent can be cut from a solid Nitinol tube (FF5), thus, the designation of any particular portion as a "strut" or a "connector" is essentially arbitrary - with the stipulation that any given portion cannot simultaneously be both a strut and a connector. That being the case, we agree with the Examiner that one can trace out adjacent, sinusoidal struts that extend along the longitudinal axis of the stent, and are connected by interconnecting members, as shown below in the Examiner's annotated version of Roubin's Figure that accompanied the Final Rejection and the Answer (Attachment #2):




As interpreted by the Examiner, longitudinal struts with multiple peaks and valleys are represented by heavy, dark lines, while elements 44 on the left side of the figure are interconnecting members that connect adjacent struts, as are elements 42 on the right side of the figure (elements 42 on the left side are incorporated into the struts in this scenario, as are elements 44 on the right side).

Appellants have not explained why the Examiner's designation of these elements as struts and interconnecting members is incorrect. That being the case, the question that remains is whether the interconnecting

members "interconnect[] adjacent pairs of struts and extend[] between a peak of a first strut and a valley of a second strut" as required by the claims.

On this point, we agree with Appellants that the Examiner's "annotations on FIG. 4A . . . indicate that the left 'interconnecting member' connects a 'valley' at a top left end thereof to another 'valley' at a bottom right end thereof" (App. Br. 16), thus, "Roubin does not disclose a 'plurality of interconnecting members interconnecting adjacent pairs of struts and extending between a peak of a first strut and a valley of a second strut,'" as required by the claims.

The rejection of claims 1-4, 8, and 18 as anticipated by Roubin is reversed.

OBVIOUSNESS

Obviousness rejections III and IV are based on the Examiner's underlying finding that adjacent struts in Kanesaka's device are arranged in an "in-phase relationship . . . about a circumferential aspect" of the device (Ans. 6, 8). Alternatively, rejections III and IV are based on the Examiner's underlying finding that Roubin discloses a stent with interconnecting members interconnecting adjacent pairs of sinusoidal struts and extending between a peak of a first strut and a valley of a second strut (*id.* at 7, 8).

As we have determined that that the record does not support either of these findings, and the Examiner has not explained how the deficiencies are made up by Smith or Whitcher, we will reverse these rejections as well.

INDEFINITENESS

According to the Examiner, "[i]t is unclear how each strut has tapered end regions, when the independent claim describes the struts as each

extending the entire length of the device (not just between a peak and a valley), and the ends of the stent are not shown as tapered" (Ans. 5).

Appellants do not challenge the propriety of this rejection. Rather, Appellants acknowledge that "the bodies of claims 14 and 15 are transposed and include errors that arose when amendments were made thereto" (App. Br. 30).

The rejection of claims 14-17 as indefinite is affirmed.

SUMMARY

I. The rejection of claims 1-4 and 14-18 as anticipated by Kanesaka is reversed.

II. The rejection of claims 1-4, 8, and 18 as anticipated by Roubin is reversed.

III. The rejection of claims 5-7 and 9-11 as unpatentable over Kanesaka or Roubin, in view of Smith is reversed.

IV. The rejection of claims 7 and 9-11 as unpatentable over Kanesaka or Roubin, in view of Whitcher is reversed.

V. The rejection of claims 14-17 as indefinite is affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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