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SEAGER, TUFTE & WICKHEM, LLP
100 South 5th Street
Suite 600
Minneapolis, MN 55402

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BACHMAN, LINDSEY MICHELE	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ERIK J. VAN DER BURG, DINO DE CICCO, ANDREW G.C. FRAZIER, ALEXANDER K. KHAIRKHAHAN, MARC S. KREIDLER, MICHAEL D. LESH, and CHAD C. ROUE

Appeal 2020-000358
Application 15/333,945
Technology Center 3700

Before BENJAMIN D. M. WOOD, WILLIAM A. CAPP, and LISA M. GUIJT, *Administrative Patent Judges*.

GUIJT, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant[1] seeks our review under 35 U.S.C. § 134(a) of the rejection of claims 2–4 and 6–22. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Boston Scientific Scimed, Inc. as the real party in interest. Appeal Br. 4.

THE INVENTION

Appellant's invention relates to a "System for Left Atrial Appendage Occlusion." Spec., Title. Claim 1, reproduced below as the sole independent claim on appeal, is illustrative of the subject matter on appeal.

> 1. A device configured for implantation in a left atrial appendage, the device comprising:
>
> a membrane support structure having a radially compressed configuration and a radially expanded configuration, wherein the membrane support structure has a distal end and defines a proximal diameter in the radially expanded configuration;
>
> a membrane extending across at least part of a proximal portion of the membrane support structure; and
>
> one or more distal anchoring segments configured to engage a wall of the left atrial appendage which one or more distal anchoring segments extend distally from the distal end of the membrane support structure in the radially expanded configuration,
>
> wherein in the radially expanded configuration the one or more distal anchoring segments define a distal diameter which is less than the proximal diameter of the membrane support structure.

THE REJECTIONS

The Examiner relies upon the following as evidence in support of the rejections:

NAME	REFERENCE	DATE
Simon	US 5,669,933	Sept. 23, 1997
Daniel	US 5,814,064	Sept. 29, 1998
Ambrisco	US 6,007,557	Dec. 28, 1999
Brooks	US 6,346,116 B1	Feb. 12, 2002

The following rejections are before us for review:

I. Claims 2, 4, 6–9, and 15–22 stand rejected under 35 U.S.C. § 102(b) as anticipated by Simon.

II. Claim 3 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Simon.

III. Claims 10 and 14 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Simon and Ambrisco.

IV. Claims 11 and 12 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Simon and Daniel.

V. Claims 13 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Simon and Brooks.

OPINION

Rejection I

Appellant argues claims 2, 4, 6–9, and 15–22 as a group. Appeal Br. 6–10. We select independent claim 2 as representative, and claims 4, 6–9, and 15–22 stand or fall therewith. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Regarding independent claim 2, the Examiner finds that Simon discloses a device (i.e., blood clot filter 10) comprising a membrane support structure (i.e., filter basket section 16) having radially compressed and radially expanded configurations, and also a distal end (i.e., "area between elements 14 and 16") and a proximal diameter in the radially expanded configuration. Final Act. 4–5 (citing Simon 3:46–58, Figs. 1, 2). The Examiner also finds that Simon discloses a membrane (i.e., flexible mesh 30) extending across at least part of a proximal portion of the

membrane support structure (i.e., filter basket section 16), and distal anchoring segments (i.e., wires 18) configured to engage a wall of the left atrial appendage and extending distally from the distal end of the membrane support structure in the radially expanded configuration. *Id.* at 5 (citing Simon, Figs. 1, 2, 4). The Examiner explains that Simon's distal anchoring segments (i.e., wires 18) are *configured to* engage *a wall of the left atrial appendage*, as claimed, because "the anchoring segments extend outwardly from the support structure." *Id.* The Examiner further finds that Simon discloses that, in the radially expanded configuration, the distal anchoring segments (i.e., wires 18) define a distal diameter which is less than the proximal diameter of the membrane support structure. *Id.* (citing, Simon, Fig. 2). The Examiner determines that "[t]he terms 'distal' and 'proximal' are well known in the art to be *relative* terms to describe parts of the human body, surgical tool and implants and do not impart a *structural* limitation."[2] Ans. 4.

[2] The Examiner's reliance on U.S. Pat. No. 4,425,908 is unnecessary to the Examiner's rejection of claim 2 as stated in the Final Office Action. Ans. 5–6. Notwithstanding, we are not persuaded by Appellant's argument that the Examiner improperly relied on a new reference (i.e., U.S. Pat. 4,425,908) without including the new reference in the statement of the rejection or indicating that the new reference is a new ground of rejection. Reply Br. 2. Simon expressly discloses use of the insertion tool disclosed in U.S. Pat. 4,425,908, such that Appellant is on notice regarding the subject matter of U.S. Pat. 4,425,908 relative to Simon's blood clot filter. Simon 6:46–48 ("[t]he filter may be positioned initially within a vessel by known delivery devices such as the one shown in U.S. Pat. No. 4,425,908"). In addition, allegations that an examiner's answer contains undesignated new grounds of rejection must be resolved by filing a petition to reopen prosecution under 37 C.F.R. § 1.181, the absence of which constitutes waiver of such arguments. 37 C.F.R. §41.40 ("Failure of appellant to timely file such a petition will constitute a waiver of any arguments that a rejection must be

Appellant argues that the Examiner errs by assigning a distal-proximal reference system inconsistent with the "ordinary and common meanings as used by the art of medical devices" and also inconsistent with the "self-consistent usage" of the terms proximal and distal in the Specification (with particular reference to the Figures) and claims. Appeal Br. 7; Reply Br. 4–7. In particular, Appellant submits that, with reference to Figure 4 of Simon, the Examiner "erroneously identified [optional flexible mesh 30] as corresponding to the membrane of instant claim 2," which "is explicitly attached to second filter basket section 16." Appeal Br. 7. Appellant submits that, conventionally, the claim term "distal" "refers to the portion of the device distant from the point of reference" and the claim term "proximal" "refers to the portion proximate the point of reference" (*id.* at 6), and thus, a person of ordinary skill in the art would understand Simon's device, according to Appellant's annotated Figure 7 of Simon below, wherein "[the] second filter basket section 16 is distally remote from the proximal operator's handle" (*id.* at 8).

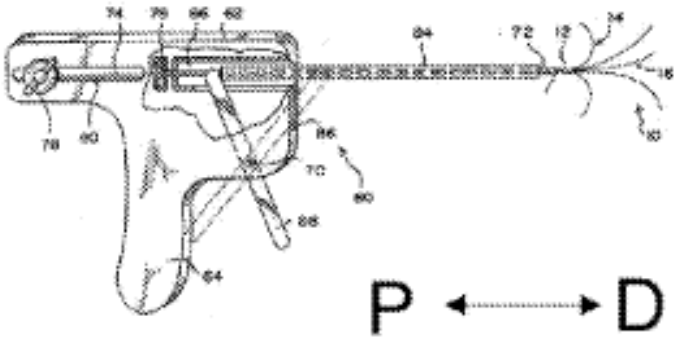

FIG. 7

designated as a new ground of rejection."); *accord* MPEP § 1207.03. Appellant did not file a petition and, therefore, waived any argument that the Examiner's Answer includes new grounds of rejection.

Appellant's annotated Figure 7 of Simon depicts a removal tool for blood clot filter 10 and includes Appellant's arrows identifying proximal and distal directions with respect to the removal tool, such that second filter basket section 16 is distal from (or situated away from) the point of attachment to the removal tool. *Id.* at 6; Simon 3:28–29, Fig. 7. Appellant submits that "[o]ne of ordinary skill in the art of left atrial appendage occlusion devices would have known that a transvenous approach to the left atrial appendage would dictate the instantly indicated implantation approach direction in which the distal end of the device enters the left atrial appendage first." Reply Br. 3.

We are not persuaded by Appellant's argument. The Examiner is correct in that claim 2 does not specify a structure for referencing the proximal diameter or portion, and distal end of the membrane support structure, which can be relied on to distinguish the claimed device from Simon's device, in view of the proximal and distal positions assigned by the Examiner to Simon's device. Thus, claim 2 reads on Simon's blood clotting device.

Appellant also argues that Figure 4 of Simon is the only figure depicting mesh 30, which the Examiner "erroneously identified . . . as corresponding to the membrane of instant claim 2." Appeal Br. 7; *see also id.* at 12 ("Simon does not teach a membrane but instead teaches an optional mesh 30"). To the extent Appellant is arguing that Simon's mesh does not disclose a membrane, Appellant does not provide sufficient argument or evidence as to *why* Simon's mesh is not, structurally, also a membrane. To the contrary, the prior art recognizes that mesh *is* considered a membrane: "[*m*]*esh* 22 is preferably formed of woven or braided fibers or wires, or a

microporous *membrane*, or other suitable filtering or netting-type material," and more particularly, "mesh **22** *is* a microporous membrane having holes therein with a diameter of approximately 100 μm." Daniel 3:33–37 (emphasis added).

Appellant also argues that

> one of ordinary skill in the art would not view the temporary venous filter of Simon, explicitly described as a removable implant, *as directed toward the same field of art* as a left atrial appendage implanted for reducing the risk of thrombus formation in and release from a left atrial appendage through occluding the atrial appendage opening, optionally through tissue ingrowth.

Appeal Br. 9 (emphasis added). Appellant submits that

> one of ordinary skill in the art *would not have turned to* . . . venous filter references . . . disclosing designs which result in substantially unimpeded axial flow of blood through the respective lumens, for guidance in designing an occlusive element for implantation in a left atrial appendage, especially given the clearly different geometries of the implantation sites for the two categories of devices, i.e., an open tubular vein vs, a closed-end tapered left atrial appendage.

Reply Br. 2 (emphasis added).

To the extent Appellant is arguing that Simon is non-analogous and therefore, improperly relied on by the Examiner, Appellant's argument is misplaced. The test to determine whether a reference is analogous is relevant to an obviousness determination, but not to an anticipation rejection. *See Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) ("[T]he question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis."); *see also In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997) ("[T]he question whether a reference is analogous art is irrelevant to whether that reference

anticipates."). Here, not only is the Examiner's reliance on U.S. Pat. 4,425,908 unnecessary (and alternatively, only evidentiary), but the Examiner is not proposing any modification to Simon's blood clot filter in view of any prior art, but states a prima facie case that claim 2 is anticipated by Simon pursuant to 35 U.S.C. § 102(a)(1).

Appellant further argues that Simon fails to disclose that Simon's anchoring segments are *configured to* engage a wall *of the left atrial appendage*, as required by claim 2. Appeal Br. 9. Appellant submits that this claim recitation is not "merely intended use, . . . but rather imparts meaningful limitations upon the structure of the device, which limitations are related to the dimensions and structure of an expressly recited left atrial appendage." *Id.* Appellant submits that

> one of ordinary skill in the art would be aware that a generally cylindrical venous filter of uniform diameter along its length, which could be appropriate for deployment within a tubular vein would not necessarily be adapted to engage and be retained within a left atrial appendage. For example, were the overall cylindrical filter of Figs. 1 and 2 of Simon to be sized to have an expanded diameter appropriate to engaging the wall of a left atrial appendage deep within the left atrial appendage while maintaining the length to diameter ratio indicated by the various figures of Simon, the distal basket 14 would not be expected to have a diameter large enough to span the ostium of the left atrial appendage at the device's proximal end. One of ordinary skill in the art would be well aware that this mismatch between the geometry of a vein and the left atrial appendage and would be aware that a venous filter of Simon when inserted into a left atrial appendage would be unsuited for filtering blood flow into and out of the left atrial appendage or for the instant purpose of occluding the flow of debris out of the left atrial appendage as taught by the instant invention.

Reply Br. 8–9.

We are not persuaded by Appellant's argument. The Specification discloses that "[f]or patients who develop atrial thrombus from atrial fibrillation, the clot normally occurs in the left atrial appendage (LAA) of the heart," wherein "[t]he LAA is a cavity which looks like a small finger or windsock and which is connected to the lateral wall of the left atrium." Spec. 1:25–27. The Specification also discloses that

> FIG. 4 depicts an occluding device 30 similar to that depicted in FIGS. 1-3 deployed within the left atrial appendage 31 of a patient. An outer rim or periphery 32 of the occluding device 30 is disposed adjacent the opening 33 of the left atrial appendage 31 in a position which allows for a substantial seal of the outer rim against the inside surface 34 of the LAA. A helically shaped distal extremity 35 of a tissue penetrating shaft 36 has been screwed into the wall tissue of the LAA and is mechanically secured thereto. A retention member 38 maintains the position of an occluding member 41 in a substantially perpendicular orientation with respect to a longitudinal axis of the LAA 42.

Spec. 11:24–31. Figure 4 is reproduced below.

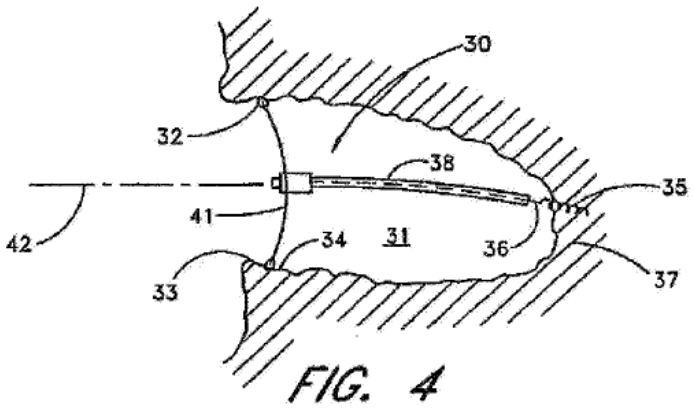

FIG. 4

Figure 4 depicts "an elevational view of an apparatus having features of the invention in a deployed state within a body cavity." Spec. 5:26–27.

In comparison, Simon discloses, with reference to Figure 2 reproduced below (rotated to correspond to the orientation of the device depicted in Figure 4 *supra*), that "two filter sections provide peripheral

portions which engage the inner wall of the vein at two longitudinal spaced locations." Simon 3:63–65.

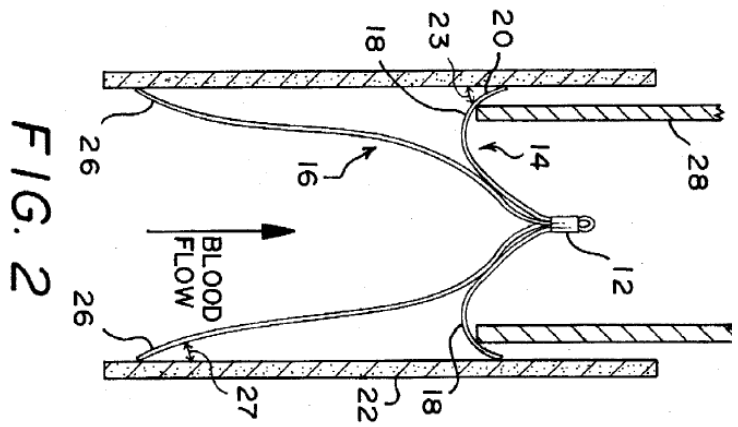

FIG. 2

Figure 2 of Simon depicts a filter "in place within a vessel." *Id.* at 3:17–18. Simon discloses that "first filter basket section **14** is formed from short, arcuate lengths of wire **18** which form arms that curve downwardly, outwardly and upwardly from the hub **12** toward the trailing end of the filter **10**," wherein "tip sections **20** of the wires **18** are substantially straight lengths with ends which lie on a circle at their maximum divergence and the tip sections engage the wall **22** of a vessel at a slight angle **23** . . . to anchor the filter **10** against upward movement." *Id.* 4:1–8. Although Simon is silent with respect to placement of Simon's device within a left atrial appendage, which has a closed end, as compared to an open-ended vein, Appellant does not provide sufficient argument or evidence as to why Simon's wires 18 are not also configured to engage a wall of the left atrial appendage. In other words, Appellant does not identify any structure relative to Simon's wires 18 which distinguish Simon's wires 18 from the distal anchoring segments disclosed in the Specification, or which would cause wires 18 *not* to engage a wall of the left atrial appendage.

Accordingly, we sustain the Examiner's rejection of independent claim 2, and claims 4, 6–9, and 15–22 fall therewith.

Rejection II

Claim 3, which depends from independent claim 2, recites, in relevant part, "wherein the one or more distal anchoring segments extend radially outward in a proximal direction in the radially expanded configuration." Appeal Br. 15 (Claims App.). The Examiner finds that Simon teaches "an alternate embodiment," with reference to Figures 5 and 6, wherein a distal anchoring segment (i.e., first filter basket 40) extends radially outwardly in a proximal direction in an expanded configuration, as claimed. Final Act. 7. The Examiner reasons that it would have been obvious to have used such a "known technique" and that positioning the segments as claimed would have been within "the ordinary capabilities of one skilled in the art." Final Act. 7–8.

Appellant argues that, similar to claim 2 *supra*, wire segments 16, 18, with particular reference to Figures 5 and 6, "as a whole extend distally radially outward when viewed relative to the directional convention of the instant specification and claims." Appeal Br. 10–11. Appellant also argues that "there is no articulated motivation to modify the apparently fully functional filters of Simon by a proximal-to-distal inversion, as articulated by the Examiner, with a reasonable expectation of success for the purpose of Simon." *Id.* at 11.

We are not persuaded by Appellants argument, in that we do not agree that the Examiner erred by assigning the proximal-distal reference system as set forth in the Examiner's rejection and as discussed *supra* with respect to independent claim 2. Further, we find that wires 18, as depicted in

Figures 4, and wires arms 38, as depicted in Figures 5 and 6, have *portions* that extend radially outwardly in a proximal direction, as claimed, as well as *portions* that extend radially outwardly in a distal direction, such that claim 3 reads on Simon's wires 18. Regarding Appellant's argument addressing the Examiner's lack of "articulated motivation," we disagree that the Examiner failed to provide reasoning, to the extent Simon's Figure 4 embodiment requires modification, in that the Examiner reasons, in sum, that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *See KSR Int'l Co. v. Tele-flex Inc.*, 550 U.S. 398, 416 (2007).

Accordingly, we sustain the Examiner's rejection of claim 3.

Rejection III

Claims 10 and 14, which depend from independent claim 2, recite, in relevant part, "wherein the membrane is a barrier membrane" and "wherein the membrane is formed as a composite laminate," respectively. Appeal Br. 16 (Claim App.). The Examiner finds that Simon discloses a membrane, but not a *barrier* membrane or a membrane formed as a *composite laminate*, and the Examiner relies on Ambrisco for teaching that "the filtering material can be in the form of a . . . barrier membrane (because it resists tissue ingrowth) or a laminate (because it is disclosed as being layered)." Final act. 7–8 (citing Ambrisco 3:10–30). The Examiner reasons that it would have been obvious to modify Simon's membrane, as taught in Ambrisco, because "the particular known technique of composite filter membranes and drug-coated filter membranes was recognized as part of the ordinary capabilities of one skilled in the art." Final Act. 8.

Appellant argues that "Simon does not teach a membrane and instead teaches an optional mesh 30," and further, that Ambrisco does not teach "a composite laminate" or "a barrier membrane." Appeal Br. 11 (citing Ambrisco 3:10–30).

As discussed *supra* Simon discloses a mesh, which the prior art considers a membrane, and also that "mesh **30** will permit blood to pass through the section 16 *but will capture* bone chips and small particles which might otherwise pass between the wires **24** and **18**." Simon 4:16–5:5 (emphasis added). Thus, Simon discloses a membrane that serves as *a barrier* to bone chips and small particles, and we are not apprised by Appellant as to why Simon's membrane does not qualify as a barrier membrane. Notwithstanding, the Examiner relies on Ambrisco, which discloses that "filter mesh pore sizes ideally range[] from 40 to 120 microns, but other sizes may be used," suggesting that the mesh may be selected *to block* the passage of *certain* material, the characteristic ascribed to barrier 15 by the Specification. Ambrisco 3:13–14; *see also id.* at 20:28–30 ("[o]cclusion techniques include reducing the mesh pore size, and thereby the permeability of the mesh"). In sum, we are not apprised of error in the Examiner's finding that claim 10 is obvious in view of Simon and Ambrisco.

Regarding claim 14, the Specification also discloses that "bonding layer 254 preferably comprises a mesh or other porous structure having an open surface area," which is "positioned in-between a first membrane 250 and a second membrane 252 to provide a composite stack." *Id.* 20:27–21:12. In other words, we are not apprised of error in the Examiner's finding that the claim term "composite" means layered. Ambrisco discloses that "[t]he mesh," which as discussed *supra* is considered a membrane in the

prior art, may be "layered," and thus, Appellant's recitation of the claim language does not apprise us of error in the Examiner's finding or reasoning. Notably, statements that merely point out what a claim recites are not considered to present an argument for separate patentability of the claim. 37 C.F.R. § 41.37(c)(1)(iv); *see also In re Lovin*, 652 F.3d 1349, 1357 (Fed. Cir. 2011) (Rule 41.37 requires more than recitation of the claim elements and a naked assertion that the elements are not found in the prior art).

Accordingly, we sustain the Examiner's rejection of claims 10 and 14.

Rejection IV

Claims 11 and 12, which depend from independent claim 2, recite, in relevant part, "wherein the membrane is a porous membrane" and "wherein the membrane includes opening or pores within a range of from about 0.0005 inches to about 0.010 inches," respectively. Appeal Br. 16 (Claim App.). The Examiner finds that Daniel discloses a porous membrane (i.e., 22) with openings in the claimed range, because "this allows blood to flow through but retains stenosis fragments carried in the blood flow." Final Act. 9. The Examiner reasons that it would have been obvious to have modified Simon's filter, as taught by Daniel, to allow blood to flow through the filter, but to retain stenosis fragments carried in the blood flow. *Id.*

Appellant argues that "Simon does not teach a membrane and instead teaches an optional mesh 30," which as discussed *supra*, we do not find persuasive. Appellant also argues that "there is no motivation to combine the teaching of Simon and Daniel." Appeal Br. 12. Appellant submits that "the presence of a membrane of unspecified fractional openness in a venous filter would be expected to undesirably occlude a vessel in which it might be deployed, such as a vena cava, thereby rendering the device unsatisfactory

for its intended purpose." *Id.* However, Appellant does not provide sufficient argument or evidence that modifying the pores sizes of Simon's mesh 30, as taught in Daniel, would cause Simon's mesh to function unsatisfactorily as a blood clot filter.

Accordingly, we sustain the Examiner's rejection of claims 11 and 12.

Rejection V

Claim 13, which depends from independent claim 2, recites, in relevant part, "wherein the membrane is formed from materials which facilitate cellular in-growth." Appeal Br. 16 (Claims App.). The Examiner relies on Brooks for teaching a filter membrane made of ePTFE, which is a material disclosed in the Specification as resisting tissue in-growth.[3] Final Act. 9 (citing Brooks 3:62–64, 4:3–6; Spec. 20:15–20). The Examiner reasons that it would have been obvious to make Simon's filter from ePTFE, as taught by Brooks, because "the particular known technique of using ePTFE as a filter membrane was recognized as part of the ordinary capabilities of one skilled in the art." *Id.*

Appellant argues that the Examiner improperly relied on Appellant's Specification and mischaracterized Appellant's Specification "as disclosing that ePTFE resists tissue ingrowth." Appeal Br. 13. In particular, Appellant submits that the Specification discloses that "barrier 15 may comprise any of a variety of materials which facilitate cellular in-growth, such as ePTFE." Appeal Br. 13.

[3] The Examiner states that, in the Final Rejection, the Examiner meant to find that that ePTFE is a material disclosed in the Specification for *facilitating*, not *resisting*, tissue in-growth. Ans. 10 ("should say 'facilitate'").

We are not persuaded by Appellant's argument. Indeed, Brooks discloses that "suitable filter materials may include . . . ePTFE . . . and the like having an appropriate porous construction to filter emboli from blood passing through the filter" (Brooks 4:3–6), and the Specification discloses that "barrier 15 may comprise any of a variety of materials which facilitate cellular in-growth such as ePTFE" (Spec. 20:16–17). The Examiner may properly rely on the Specification for disclosing that it is known that ePTFE is one of a variety of materials recognized for facilitating cellular in-growth.

Accordingly, we sustain the Examiner's rejection of claim 13.

CONCLUSION

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)**	**Affirmed**	**Reversed**
2, 4, 6–9, 15–22	102(b)	Simon	2, 4, 6–9, 15–22	
3	103(a)	Simon	3	
10, 14	103(a)	Simon and Ambrisco	10, 14	
11, 12	103(a)	Simon and Daniel	11, 12	
13	103(a)	Simon and Brooks	13	
Overall Outcome			2–4, 6–22	

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED