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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TRACEE EIDENSCHINK

Appeal 2018-000427[1]
Application 14/178,780
Technology Center 3700

Before KEVIN F. TURNER, EDWARD A. BROWN, and
LEE L. STEPINA, *Administrative Patent Judges*.

STEPINA, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134(a) from the Examiner's decision to reject claims 1–6, 8, 9, 13, and 16–19.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] St. Jude Medical, Cardiology Division, Inc. is the Appellant and is listed in the Appeal Brief as the real party in interest. Appeal Br. 2.
[2] Claims 7, 10–12, 14, and 15 are withdrawn. Appeal Br. 10–11 (Claims App.).

CLAIMED SUBJECT MATTER

The claims are directed to a system and method for filtering and removing debris from the bloodstream of a patient. Spec. ¶ 2. Claims 1 and 18, reproduced below with emphases added, are illustrative of the claimed subject matter:

> 1. A vessel protector, comprising:
>
> a body formed from a filtering material, the body having a collapsed configuration and a tubular expanded configuration with an open proximal end and an open distal end, and *having openings of a size no smaller than about 80 um^2 and no larger than about 300 um^2*;
>
> a first snare attached to one end of the body; and
>
> a first pull-wire connected to the first snare, whereby the exertion of a pulling force on the first pull-wire contracts the first snare and thereby closes the one end of the body.

Appeal Br. 10 (Claims App.).[3]

> 18. A method for protecting blood vessels during a medical procedure, comprising:
>
> inserting a vessel protector system into a patient's body, the vessel protector system including a vessel protector and a sheath, the vessel protector having a body formed from a filtering material, the body having a collapsed configuration and a tubular expanded configuration, and *having openings of a size no smaller than about 80 um^2 and no larger than about 300 um^2*, and the sheath being movable relative to the body between a first position for holding the body in the collapsed configuration, and a second position for releasing the body for movement to the expanded configuration;
>
> positioning the vessel protector system adjacent an open end of at least one blood vessel; and
>
> moving the sheath to the second position to deploy the body, whereby the body moves to the tubular expanded configuration covering the open end of the at least one blood

[3] Appellant uses the units "um" to indicate "μm" and "um^2" to indicate "μm^2."

vessel to filter blood passing through the body into the at least one blood vessel.

Id. at 12.

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Yodfat	US 2003/0125801 A1	July 3, 2003
Sepetka	US 6,663,650 B2	Dec. 16, 2003
Brady	US 2006/0276887 A1	Dec. 7, 2006
Greenberg	US 2007/0055365 A1	Mar. 8, 2007
Adams	US 2014/0249568 A1	Sept. 4, 2014

REJECTIONS

I. Claims 1–6, 8, 9, 13, and 16–19 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

II. Claims 18 and 19 are rejected under 35 U.S.C. § 103(a) as unpatentable over Yodfat and Greenberg.

III. Claims 18 and 19 are rejected under 35 U.S.C. § 103(a) as unpatentable over Adams and Greenberg.

IV. Claims 1–6, 8, 9, 13, and 16 are rejected under 35 U.S.C. § 103(a) as unpatentable over Yodfat, Greenberg, and Brady.

V. Claims 1–6, 8, 9, 13, 16, and 17 are rejected under 35 U.S.C. § 103(a) as unpatentable over Adams, Greenberg, and Sepetka.

OPINION

Rejection I, Indefiniteness

The Examiner determines that the term "about," as recited before the endpoints of the numerical ranges in each of independent claims 1, 16, and 18, renders these claims indefinite. *See* Final Act. 7–8. Specifically, the Examiner states, "the instant specification fails to disclose with sufficient

specificity the degree to which the term 'about' should be afforded." *Id.* The Examiner likens claims 1, 16, and 18 to claims that were determined to be indefinite in *Amgen, Inc. v. Chugai Pharm Co., Ltd.*, 927 F.2d 1200 (Fed. Cir. 1991). *Id.* at 3–4.

Appellant contends "one of ordinary skill in the art would know that the claims' recitation of 'about' in the terms 'about 80 um^2' and 'about 300 um^2' is intended to account for the manufacturing variation, or 'tolerance,' in the size of the openings," and "infringement of the claims could be clearly determined by measuring the size of the openings of an accused device." Appeal Br. 5. Appellant asserts that the term "about" as recited in the independent claims merely reflects the practicalities of manufacturing a filter material, and, in the context of the recited limitations, a person of ordinary skill in the art would understand this. *Id.* at 6.

In response, the Examiner finds that Greenberg qualifies as "close prior art" as discussed in *Amgen*, and, therefore, given the lack of guidance provided by the Specification as to the meaning of the term "about" in claims 1, 16, and 18, these claims are properly rejected as indefinite. Ans. 4–5; *see also Amgen*, 927 F.2d at 1218.

Appellant has the better position. The decision in *Amgen* included an explicit caution that the holding therein "should not be understood as ruling out any and all uses of [the term 'about'] in patent claims. It may be acceptable in appropriate fact situations … even though it is not here." *Amgen*, 927 F.2d at 1218. The Court also indicated that even without the use of the term "about," the claims at issue were indefinite. *Id.* at 1218. The Court's cautionary language highlights that the determination of indefiniteness based on the use of the word "about" is to be based on the facts presented in each case. In *Amgen*, the two principal factors that the

Court found probative were that the only available method to measure the "specific activity" that was claimed using the term of degree "about" was itself an imprecise form of measurement and that the term "about" was a significant factor in the patentee's ability to obtain allowance of the claims at issue over the prior art. *Id.* at 1217–1218. Here, the cross-sectional areas of the pores of the filter material are readily susceptible of being accurately measured by any number of methods inasmuch as they relate to physical dimensions of the pores. Further, as will be seen in the ensuing discussion of the rejections based on the prior art, the claimed size of the openings is not critical to the patentability of the claims. As such, the outcome in *Amgen* is not particularly germane to the present situation. For these reasons, we do not sustain this rejection.

Rejection II, Yodfat and Greenberg

(a)

The Examiner relies on Yodfat to teach many of the elements recited in claim 18, but relies on Greenberg to teach that, in a blood filtering element, a "pore diameter should be at least 10μm and preferably 20μm in diameter . . . which would provide an open size range of 78.5 μm^2–314 μm^2." Final Act. 9–10; *see also* Greenberg ¶ 5. Further, the Examiner determines that "[i]t would have been obvious to . . . provide the filtering deflecting means of Adams with the open size range as disclosed by Greenberg since Greenberg discloses that this opening size is preferable for allowing blood flow while preventing the passage of clots and emboli (paragraph 5)." Final Act. 10–11.

Appellant argues that the Examiner erred in finding that Greenberg discloses that the size of the pores in its filter media are preferably 20 μm in

diameter. Appeal Br. 8. Specifically, Appellant asserts, "Greenberg's paragraph [0005] does not disclose 'openings of a size . . . no larger than about 300 um^2,' but rather, discloses pores of at least 10 um in diameter (area of 78.5 um^2) or pores of **at least** 20 um in diameter (area of 314 um^2)." *Id.*

In response, the Examiner states:

> Greenberg teaches pores that encompass the disclosed range of between about 80μm^2 and about 300μm^2 which corresponds to no smaller than about 80μm^2 and no larger than about 300μm^2 by teaching "pores of at least 10 μm in diameter (area of 78.5 μm^2)" which discloses openings which are no smaller than about 80μm^2 and no larger than about 300μm^2.

Ans. 9 (emphasis omitted). Thus, the Examiner finds that Greenberg's disclosure of pores having diameters of at least 10 μm (areas of at least 78.5 μm^2) satisfies the pore size requirement in claim 18 because this disclosure teaches pore sizes falling *within* (as well as above) the recited 80 μm^2–300 μm^2 range. Accordingly, the Examiner implicitly interprets claim 18 as allowing for pore sizes to also *exceed* the 300 μm^2 upper limit of the range.

In reply, Appellant contends that the range of pore sizes set forth in claim 18 applies to all the pores in the filter material, i.e., that the filter material does not allow passage of particles larger than the 300 μm^2 upper limit. *See* Reply Br. 1–3. Consequently, according to Appellant, the disclosure in Greenberg of filter material having pores with diameters of at least 10 μm (areas of at least 78.5 μm^2) fails to meet the requirement that the pores have openings of a size no smaller than about 80 μm^2 and no larger than about 300 μm^2. *See id.*

During examination of a patent application, pending claims are given their broadest reasonable construction consistent with the Specification. *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

> The correct inquiry in giving a claim term its broadest reasonable interpretation in light of the specification is not whether the specification proscribes or precludes some broad reading of the claim term adopted by the examiner. And it is not simply an interpretation that is not inconsistent with the specification. It is an interpretation that corresponds with what and how the inventor describes his invention in the specification, i.e., an interpretation that is "consistent with the specification."

In re Smith Int'l, Inc., 871 F.3d 1375, 1382–1383 (Fed. Cir. 2017) (quoting *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997)). Claim 18 recites a method for protecting blood vessels during a medical procedure. Appeal Br. 12 (Claims App.). Paragraphs 20 and 21 of the Specification describe accomplishing this function by *blocking* particulates that are greater than a certain size while allowing the passage of blood, and paragraph 21 explains that openings in the filter material having a size of "between about 80 μm^2 and 300 μm^2" perform this function. This discussion in paragraph 21 is the only place in the Specification that mentions the recited 80 μm^2–300 μm^2 pore size range. Accordingly, the broadest reasonable interpretation of claim 18, consistent with the Specification, precludes using a filter material having pore sizes greater than 300 μm^2 inasmuch as the purpose of the filter material is to block particulate, and having pore sizes larger than 300 μm^2 would, by passing relatively large particles, frustrate the blocking effect of having pores with sizes inside the recited range. Consequently, the Examiner's finding that Greenberg's disclosure of pores having diameters of at least 10 μm (areas of at least 78.5 μm^2) satisfies the pore size requirement in claim 18 is based on an unreasonably broad interpretation of claim 18.

(b)

The Examiner provides an alternate basis for rejecting claim 18, namely, that in light of the teachings of Yodfat and Greenberg, a person of ordinary skill in the art would have recognized the size of pores in a filter material as a result-effective variable. Final Act. 11. Specifically, the Examiner finds Greenberg teaches open pore sizes may be in the recited range "for the purpose of preventing the passage of clots and emboli." *Id.* (citing Greenberg ¶ 5). From this, the Examiner determines that it would have been obvious to a person of ordinary skill in the art, as a matter of routine optimization, "to provide the openings of a size no smaller than about 80 μm^2 and no larger than about 300 μm^2, for the purpose of preventing the passage of clots and emboli." *Id.* (citing *In re Aller*, 220 F.2d 454 (CCPA 1955)).

Appellant does not specifically discuss the Examiner's alternate basis for rejecting claim 18. *See* Appeal Br. 7–9; Reply Br. 1–3. However, Appellant asserts that Greenberg teaches away from providing an upper limit of 300 μm^2 by disclosing that a pore diameter of at least 20 μm (an area of 314 μm^2) is preferred. Appeal Br. 8. Appellant contends that this disclosure in Greenberg encourages the use of pore sizes of 314 μm^2 and above, and, therefore, *discourages* the use of pore sizes of less than 314 μm^2. Reply Br. 2–3.

The Examiner's finding that Greenberg teaches that the size of pores in filter material is recognized as a result-effective variable for blood filtering (Final Act. 11) is supported by a preponderance of the evidence. *See* Greenberg, Abstract, ¶ 5. Further, Appellant's argument that Greenberg teaches away from the pore size range recited in claim 18 is unavailing. *See In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) ("[A] finding that the

prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed . . . is the preferred, or most desirable, combination."). The statement in Greenberg that a pore diameter of at least 20 μm (area of at least 314 μm^2) is *preferred*, but also indicating that pore diameters of at least 10 μm (areas of at least 78.5 μm^2) function to filter blood (Greenberg ¶ 5), does not amount to teaching away from the use of pore diameters sizes limited to a range of 80 μm^2 to 300 μm^2 as recited. Accordingly, we sustain the Examiner's rejection of claim 18, and claim 19 depending therefrom, as unpatentable over Yodfat and Greenberg.

Rejections III–V

The Examiner relies on the same findings of fact and reasoning regarding modifications based on Greenberg in Rejections III–V as discussed above for Rejection II. *See* Final Act. 13–16, 20–22. Appellant contends that the arguments discussed above apply to each of Rejections III–V and makes no separate arguments contesting any of these rejections. *See* Appeal Br. 7–9. Accordingly, for the same reasons discussed regarding Rejection II, we sustain Rejections III–V.

DECISION

The Examiner's decision rejecting claims 1–6, 8, 9, 13, and 16–19 is affirmed.

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