UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* ERHAN H. GUNDAY, LAWRENCE J. GERRANS, and ALEX HSIA

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Appeal 2017-004405
Application 13/480,153[1]
Technology Center 3700

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Before JOHN C. KERINS, EDWARD A. BROWN, and ARTHUR M. PESLAK, *Administrative Patent Judges*.

BROWN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Erhan H. Gunday et al. (Appellants) seek review under 35 U.S.C. § 134(a) of the Examiner's decision rejecting claims 1, 3, 4, 9–11, 15, 16, 18–36, and 40–42, which are the pending claims. Appellants' representative presented oral argument on January 8, 2019. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] Sanovas, Inc. is identified as the real party in interest. Appeal Br. 2.

## CLAIMED SUBJECT MATTER

Appellants' disclosure "generally relates to the field of medical imaging devices. In particular, the present invention relates to a system and method for cleaning a medical imaging device in situ." Spec. ¶ 2.

Claims 1, 10, and 30 are independent. Claim 1 illustrates the claimed subject matter, and reads:

> 1. An imaging catheter device comprising:
> a catheter body having a proximal end, a distal end, and a lumen;
> a cleaning member disposed at the distal end of said catheter body; and
> an imaging device movably disposed in said lumen and through said cleaning member;
> wherein said cleaning member includes a conduit through which said imaging device moves;
> wherein said cleaning member further includes a plurality of flexing flaps at least partially occluding the conduit such that said imaging device displaces at least some of the flexing flaps when moved through the conduit to clean said imaging device; and
> wherein at least one of the flexing flaps is not aligned with at least one other flexing flap.

Appeal Br. 14 (Claims App.).

## REJECTIONS

The Final Office Action includes the following rejections under 35 U.S.C. § 103(a):

Claims 1, 3, 4, 9–11, 15, 16, 18, 20–22, 25, 27–36, and 40–42 are rejected as unpatentable over Bhatta (US 5,375,589, issued Dec. 27, 1994) and Brockmeier (US 2008/0290605 A1, published Nov. 27, 2008).

Claim 19 is rejected as unpatentable over Bhatta, Brockmeier, and Byers (US 2010/0087705 A1, published Apr. 8, 2010).

Claims 23, 24, and 26 are rejected as unpatentable over Bhatta, Brockmeier, and Miller (US 2009/0105543 A1, published Apr. 23, 2009).

## ANALYSIS

### *Claims 1, 3, 4, 9–11, 15, 16, 18, 20–22, 25, 27–36, and 40–42 over Bhatta and Brockmeier*

As to claim 1, the Examiner finds that Bhatta discloses an imaging catheter device comprising a catheter body (casing 1) having a distal end, a cleaning member (cleaning means 3) disposed at the distal end and including a conduit (opening 9), and an imaging device (optical fiber 2) movably disposed in the cleaning member. Final Act. 7 (citing Bhatta, Figs. 1–3, 9). The Examiner finds that the cleaning member includes brush-like flexible surfaces, at least some of which are displaced by the imaging device when moved through the conduit to clean the imaging device, but finds that Bhatta does not explicitly disclose that the flexible surfaces are flaps, as claimed. *Id.* at 7–8 (citing Bhatta, col. 3, ll. 17–35). The Examiner finds that Brockmeier teaches a seal member including bristle members extending radially inwardly to a central longitudinal axis. Final Act. 8. The Examiner finds that Brockmeier additionally teaches flexing flaps (flat flexible components 802 of seal member 800) at least partially occluding a conduit such that an imaging device displaces at least some of the flexing flaps when moved through the conduit. *Id.* The Examiner finds that at least one flexing flap is not aligned with at least one other flexing flap. *Id.* at 8–9 (citing Brockmeier ¶ 40).

The Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify Bhatta's apparatus to include the flap-shaped bristle arrangement of Brockmeier because "using bristle-like structures partially occluding a conduit is well known in the art and suitable for use in the cleaning of surgical instrument/apparatus in the surgical field." Final Act. 9. The Examiner reasons that one of ordinary skill in the art would have been motivated to substitute Bhatta's bristles with Brockmeier's flap-shaped bristles because the combination would yield the same predictable results. *Id.*

In the Final Action, the Examiner indicates that Official Notice is taken that "the flap arrangement that seals" in Brockmeier acts as both a valve *and* a cleaning device by occluding the medical device. Final Act. 5. In support, the Examiner cites Crump.[2] However, in the Examiner's Answer, the Examiner explains that the Official Notice position based on Crump is moot because the Examiner was explaining his position in a previous rejection based on Bhatta, Byers, and Crump, which was withdrawn in the Final Action. Ans. 10 (citing Final Act. 2).

Appellants contend that the only embodiment described and illustrated in Bhatta employs a brush. Appeal Br. 6 (citing Bhatta, col. 3, ll. 31–32, Fig. 2). Appellants also contend that Brockmeier discloses a sealing mechanism designed to "'provide a substantial *seal between* a *bodily cavity of* a *patient and the atmosphere outside of the patient* while an instrument is inserted through the cannula assembly.'" *Id.* at 6–7 (citing Brockmeier ¶ 27). Appellants acknowledge the prior art use of bristle-like structures to

[2] US 6,543,451 B1, issued April, 8, 2003.

clean a surgical instrument, but contend "it does not follow that a person of skill would expect the substitution of flaps for the bristles to yield the same result of cleaning the instrument, especially in view of prior art that discloses use of flaps for an entirely different purpose of creating a seal." *Id.* at 7. Appellants assert that because Brockmeier's sealing device with flaps is designed to provide a tight seal between the surgical instrument and the outside environment, a person of skill would not expect the sealing device to clean off the surgical device by moving it back and forth through the sealing mechanism, but, to the contrary, "would expect such device to *create* a *tight seal* once the surgical instrument is inserted therein and not allow for the instrument to be displaced within the sealing mechanism to clean the instrument." *Id.* at 7–8.

To the extent Appellants are contending that Bhatta's disclosure is limited to using a brush as the cleaning means, we disagree. As noted by the Examiner, Bhatta discloses, "[a]lthough [] the preferred embodiment employs a brush, the cleaning means **3** may comprise *any flexible surface* capable of removing tissue when in frictional contact with the distal end **8** of the fiber **2**." Ans. 3; *see* Bhatta, col. 3, ll. 31–35 (emphasis added). Bhatta does not, however, disclose that the "flexible surface" may be in the form of the claimed flexing flaps.

The Examiner agrees that Brockmeier's seal assembly is adapted to provide a substantial seal between a body cavity of a patient and the atmosphere outside the patient while an instrument is inserted through the cannula assembly. Ans. 5. However, the Examiner submits that Brockmeier's sealing assembly facilitates the removal of irregularly shaped body tissue. *Id.* (citing Brockmeier ¶ 27). Appellants contest the

Examiner's interpretation of paragraph 27 of Brockmeier. Reply Br. 2. Appellants submit that a person of ordinary skill in the art would understand that this passage "is referring to the advantages of enabling removal of the irregularly shaped body tissue through the incision once the seal assembly 300 has been detached from the cannula assembly 200." *Id.* at 3.

We are persuaded that the Examiner has not established, with evidence, that there would be a reasonable expectation of success that the flexible components of Brockmeier would achieve the claimed cleaning function. Reply Br. 3. The Examiner's position is premised on the finding that the embodiment shown in Figure 16 of Brockmeier, "besides providing a sealing configuration, also provides the advantage of facilitating the removal of irregularly shaped body tissue." Ans. 7. According to the Examiner, the flexible flat components shown in Figure 16 of Brockmeier would have rendered the same predictable results of sealing and removing irregularly shaped body tissue as the bristle-like component shown in Figures 2 and 3B, as suggested by Brockmeier in paragraph 27. *Id.* at 9. However, paragraph 27 discloses that the detachability of seal assembly 300 facilitates the removal of irregularly shaped body tissue in the assembly. *See* Brockmeier ¶ 27. This paragraph does not disclose that the bristle-like component shown in Figure 2 or 3B of Brockmeier (or the flexible flat components shown in Figure 16 of Brockmeier) will also remove irregularly shaped body tissue when an imaging device displaces at least some of the flexing flaps when moved through the conduit to clean the imaging device, as required by claim 1. Accordingly, we agree with Appellants that the Examiner relies on an incorrect interpretation of paragraph 27 of Brockmeier. Reply Br. 3.

As the underlying factual basis for the rejection of claim 1 set forth by the Examiner is not supported by a preponderance of the evidence, the Examiner has not established an adequate reason with rational underpinnings to modify Bhatta in view of Brockmeier to result in the device recited in claim 1. *See In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967) (holding that "[t]he legal conclusion of obviousness must be supported by facts. Where the legal conclusion is not supported by facts it cannot stand."). Therefore, we do not sustain the rejection of claim 1, or of claims 3, 4, 9, and 10 depending therefrom, as unpatentable over Bhatta and Brockmeier.

Independent claim 11 is directed to a cleaning system for a medical imaging device comprising, in pertinent part, a cleaning member comprising "a conduit through which the imaging device moves" and "a plurality of flexing flaps at least partially occluding the conduit such that the imaging device displaces at least some of the flexing flaps when moved through the conduit." Appeal Br. 15 (Claims App.). The Examiner finds that Bhatta as modified by Brockmeier discloses these similar limitations as in claim 1. Final Act. 10. We do not sustain the rejection of claim 11, or of claims 15, 16, 18, 20–22, 25, and 27–29 depending therefrom, for reasons similar to those discussed for claim 1.

Independent claim 30 recites a method of cleaning a medical imaging device comprising, in pertinent part, the step of "cleaning the imaging device by moving at least one of the imaging device and the cleaning member relative to the other to move the imaging device through the conduit in said cleaning member such that the imaging device displaces at least some of the flexing flaps." Appeal Br. 16–17 (Claims App.). The Examiner notes that method claim 30 corresponds to apparatus claim 1 and rejects claim 30 for

the same reasons as claim 1. Final Act. 14. We do not sustain the rejection of claim 30, or of claims 31–36 or 40–42 depending therefrom, for reasons similar to those for claim 1.

*Claim 19 over Bhatta, Brockmeier, and Byers*

*Claims 23, 24, and 26 over Bhatta, Brockmeier, and Miller*

The Examiner's reliance on Byers or Miller in rejecting dependent claims 19, 23, 24, and 26 fails to cure the deficiencies in the rejection of parent claim 11. Final Act. 14–17. Accordingly, we do not sustain the rejections of claims 19, 23, 24, and 26.

## DECISION

The rejections of claims 1, 3, 4, 9–11, 15, 16, 18–36, and 40–42 are reversed.

REVERSED