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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANDREW T. SCHIEBER and IQBAL K. AHMED

Appeal 2019-002295
Application 14/440,610
Technology Center 3700

Before JENNIFER D. BAHR, EDWARD A. BROWN, and
WILLIAM A. CAPP, *Administrative Patent Judges*.

BAHR, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision (set forth in the Final Action dated April 16, 2018, hereinafter "Final Act.") rejecting claims 1–16 and 24–29. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as IVANTIS, INC. Appeal Br. 2.

CLAIMED SUBJECT MATTER

Appellant's invention is directed to an apparatus "for delivering ocular implants into the eye." Spec. ¶ 3. Claims 1 and 9 are independent and differ from each other in that claim 1 is directed to a cannula only, and claim 9 is directed to an implant and delivery system comprising both the cannula and an ocular implant. *See* Appeal Br. 8, 9 (Claims App.). Claim 1, reproduced below with italics to highlight pertinent limitations, is illustrative of the claimed subject matter.

1. A cannula for delivering an ocular implant into Schlemm's canal of an eye, comprising:

a rigid curved tube adapted to extend along a medial plane through an anterior chamber of the eye to achieve tangential entry into Schlemm's canal;

a trough portion formed by an opening extending along a distal portion of the rigid curved tube; and

an asymmetric tip disposed at a distal end of the trough portion offset from, and asymmetric about, the medial plane, the asymmetric tip being located at an intersection between an upper camming surface and a lower camming surface, the upper camming surface being configured to contact scleral tissue of the eye to guide the trough portion into Schlemm's canal, the lower camming surface being configured to contact a scleral spur of the eye to guide the trough portion into Schlemm's canal.

REFERENCES

The prior art relied upon by the Examiner is:

Villette	US 2007/0021725 A1	Jan. 25, 2007
Schieber	US 2010/0121342 A1	May 13, 2010

REJECTION

Claims 1–16 and 24–29 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Schieber and Villette.

OPINION

Independent claims 1 and 9 each recite “a rigid curved tube [(claim 1) or cannula (claim 9)] adapted to extend along a medial plane” and “an asymmetric tip disposed at a distal end of the trough portion [of the curved tube or cannula] offset from, and asymmetric about, the medial plane.” Appeal Br. 8, 9 (Claims App.). Although the term “medial plane” is typically used in the context of anatomy as referring to a vertical plane that divides an organism into symmetrical halves, we understand “medial plane,” as used in claims 1 and 9, to denote the plane that includes the central longitudinal axis of the curved tube and divides the tube into symmetrical halves. *See, e.g.*, Figs. 11B, 11D (the medial plane extending into the page and denoted by dashed line 122); Spec. ¶ 87 (describing “medial plane 122”).

The Examiner finds that Schieber discloses a cannula substantially as recited in claims 1 and 9, except that:

Schieber fails to disclose the tip is offset from and asymmetrical about the medial plane, the distal tip being in a position offset from a central axis of the trough, the asymmetric tip being asymmetric about the medial plane and the trough portion being symmetric about the medial plane, wherein the asymmetric tip is in a position offset from a central axis of the trough, the asymmetric tip being asymmetric about the medial plane and the trough portion being symmetric about the medial plane.

Final Act. 3–4. In Figure 21 of Schieber, curvature plane 2172, which passes through central axis 2164 of cannula 2108, is the medial plane of Schieber’s cannula. *See* Schieber ¶ 106. As illustrated in Figure 21, distal

end 2168 of Schieber’s cannula 2108 appears to be offset from central axis 2164, but in plane 2172.

The Examiner finds that Villette teaches a “similar cannula . . . used for the related purpose of delivering a therapeutic wherein the tip is offset from and asymmetrical about the medial plane . . . for the purpose of configuring the cannula to be advanced through the body in a manner which is less painful.” Final Act. 4 (citing Villette ¶ 25). The Examiner determines it would have been obvious to modify Schieber’s cannula

such that the tip is offset from and asymmetrical about the medial plane, the distal tip being in a position offset from a central axis of the trough, the asymmetric tip being asymmetric about the medial plane and the trough portion being symmetric about the medial plane, wherein the asymmetric tip is in a position offset from a central axis of the trough, the asymmetric tip being asymmetric about the medial plane and the trough portion being symmetric about the medial plan, in order to configure it to move through soft tissue (such as the trabecular meshwork) better.

Ans. 5.²

Appellant argues that “[n]othing in the record supports the Examiner’s rationale.” Appeal Br. 6. Appellant submits that “Villette’s needle tip was designed for a needle that is rotated during insertion” and not for a cannula, such as Schieber’s cannula, which is not rotated during insertion. *Id.* Given the differences in the manner in which the references operate, Appellant

² The Final Action does not include a statement proposing to modify Schieber in view of the teachings of Villette, much less articulate a rationale for doing so. *See* Final Act. *passim*. Rather, the Examiner’s determination that it would have been obvious to modify Schieber to dispose the distal tip offset from and asymmetric about the medial plane, and supporting rationale, appear for the first time in the Answer.

argues that “a skilled artisan would not have been motivated to modify Schieber’s cannula to include Villette’s needle tip.” *Id.* For the reasons that follow, we agree with Appellant that the Examiner has not established a sustainable case of obviousness of the subject matter of independent claims 1 and 9, or their dependent claims.

Schieber’s cannula 2108, much like Appellant’s cannula, comprises a curved distal portion (curved distal portion 2170) and is designed to be used to deliver an ocular implant into Schlemm’s canal in an eye by first advancing distal end 2168 of the cannula through the cornea of the eye so the distal end is disposed in the anterior of the eye, and then accessing Schlemm’s canal by, for example, piercing the wall of Schlemm’s canal with the distal end of the cannula. Schieber ¶¶ 66, 107. Consistent with this function, Schieber’s distal tip is “adapted to be inserted into an anterior chamber of a human subject’s eye, through trabecular meshwork and into Schlemm’s canal of the eye.” *Id.* ¶ 10. Schieber’s distal tip is neither designed nor intended to pierce tissue by being rotated.

Villette’s perforating injection needle, on the other hand, has “a first end intended to be connected to means for driving it in rotation.” Villette ¶ 13. Villette’s needle cuts “following a helical motion with a significant circumferential component corresponding to the speed of rotation of the needle and a much less significant axial component corresponding to the speed of penetration—or axial speed—of the needle. *Id.* ¶ 16. Villette’s cutting edge is designed with geometric characteristics specifically intended “for perforation and incision, a task which involves a first incision for starting a removal of tissue and then a cutting of the tissue in slices in order to accomplish the removal of the tissue.” *Id.* ¶ 15. The distal end of

Villette’s needle has main bevel 6 inclined at angle F and secondary bevel 8 arranged opposite main bevel 6 and forming with main bevel 6 cutting edge 11 and needle point 10, which “may be moved laterally relative to the axis in order to cause the angle of the point B, measured between the cutting edge 11 and the tangent T to the edge of the main bevel 6 adjacent to the cutting edge 11, to vary.” *Id.* ¶¶ 37–38 (boldface omitted). As illustrated in Figures 4A, 5, and 6A, the distal end of Villette’s needle includes two secondary bevels—first secondary bevel 8 and second secondary bevel 9. *Id.* ¶ 39. The two secondary bevels are “arranged asymmetrically relative to a median plane of the needle passing through a longitudinal axis L of the needle” in such a way that “they rejoin uniquely to form the point 20 in the form of a flat blade.” *Id.* ¶ 43 (boldface omitted). Villette teaches that, “[t]hanks to the asymmetrical arrangement of the secondary bevels and more particularly thanks to the fact that the perforating injection needle of the invention has only a single cutting edge, the needle performs better in perforating and cutting soft tissues, making it less painful.” *Id.* ¶ 25.

Given the significant differences in the way Schieber’s cannula and Villette’s needle are designed to operate, it is not apparent, and the Examiner does not adequately explain, why a person having ordinary skill in the art would have considered Villette’s teachings regarding the asymmetrical arrangement of the secondary bevels to be pertinent to Schieber’s cannula. The Examiner fails to provide sufficient evidence or technical reasoning to explain why a skilled artisan might have gleaned, from Villette’s teaching that such an asymmetrical arrangement on Villette’s distal end may perform better in perforating and cutting soft tissues using a rotating cutting motion, that offsetting the distal tip of Schieber’s cannula from the medial plane

would similarly improve the performance of Schieber's cannula in piercing the wall of Schlemm's canal.

For the above reasons, the Examiner fails to articulate a reason with some rational underpinnings to support the conclusion of obviousness of the subject matter of claims 1 and 9. Accordingly, we do not sustain the rejection of claims 1 and 9, or their dependent claims 2-8, 10-16, and 24-29, as unpatentable over Schieber and Villette.

DECISION

The Examiner's decision rejecting claim 1-16 and 24-29 is REVERSED.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
1-16, 24-29	§ 103(a) Schieber, Villette		1-16, 24-29

REVERSED