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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEVEN A. SCAMPINI
and RYAN P. OLIVA[1]

Appeal 2018-001315
Application 13/738,225
Technology Center 3700

Before MICHAEL L. HOELTER, LEE L. STEPINA, and BRENT M. DOUGAL, *Administrative Patent Judges*.

HOELTER, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

This is a decision on appeal, under 35 U.S.C. § 134(a), from the Examiner's Non-Final Rejection of claims 1, 3, 8, 13, and 14. App. Br. 2. We have jurisdiction under 35 U.S.C. § 6(b). For the reasons explained below, we REVERSE the Examiner's rejections of these claims.

THE CLAIMED SUBJECT MATTER

The disclosed subject matter pertains "to devices used for biological specimen collection, and more particularly, to a swab assembly for

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[1] "The real party in interest in this appeal is Hologic, Inc. . . ." App. Br. 2. Accordingly, for purposes of this appeal, we understand Hologic, Inc. is the Appellant.

collecting a biological specimen from a urethra, a cervix, or the like." Spec. ¶ 1. System claims 1 and 13, and method claim 8, are independent. Claim 1 is illustrative of the claims on appeal and is reproduced below.

> 1. A swab assembly for collecting a specimen from a human urethra, comprising:
>
> an elongated shaft having a proximal end and a distal end, the elongated shaft having a notch therein between its proximal and distal ends;
>
> a sheath having a proximal end and a distal end, the sheath defining a lumen extending between its proximal and distal ends, wherein at least a portion of the elongated shaft is disposed within the sheath lumen, and the sheath is slidable relative to the elongated shaft, the sheath being sized and shaped for insertion into a human urethra; and
>
> a compressible collection tip coupled to the distal end of the elongated shaft and configured for obtaining the specimen,
>
> wherein the sheath is slidable between a first position in which the shaft notch is disposed within the sheath lumen and wherein the sheath protects the elongated shaft from breaking at the notch, and a second position in which the shaft notch is exposed out of the sheath lumen, and wherein the sheath does not protect the elongated shaft from breaking at the notch,
>
> wherein the collection tip is configured to be compressed and positioned entirely within the sheath lumen during insertion of the sheath into the urethra, and
>
> wherein the collection tip expands when the collection tip is exposed out of the sheath lumen when the sheath is positioned at or near a specimen collection site within the urethra.

REFERENCES RELIED ON BY THE EXAMINER

Marshall	US 4,027,658	June 7, 1977
Sak	US 5,787,891	Aug. 4, 1998
Burg	US 2008/0077046 A1	Mar. 27, 2008

THE REJECTIONS ON APPEAL

Independent claims 1, 8, and 13, and the claims dependent therefrom, are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claims 1, 3, 8, 13, and 14 (i.e., all the claims) are rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Marshall, Sak, and Burg.

ANALYSIS

The rejection of independent claims 1, 8, and 13 as failing to comply with the written description requirement

The Examiner states that each of "[c]laims 1, 8 and 13 recite 'a human urethra'" and acknowledges that "[t]he specification uses the term 'urethra' throughout." Non-Final Act. 2; *see also* Ans. 7. However, the Examiner states that Appellant's Specification "does not refer to a human" and that the "specification is not so specific as to describe collecting a specimen from a human urethra." Non-Final Act. 2; Ans. 7. The Examiner states, "a swab is used for collecting a specimen from urethrae that do not belong to humans" in the prior art. Non-Final Act. 2; Ans. 7 (reference omitted). Thus, the Examiner reasons:

> A human urethra and the size and shape of the swab assembly relative to the human urethra were not described in the specification so as to reasonably convey to one skilled in the relevant art that a joint inventor, at the time the application was filed, had possession of the claimed invention.

Non-Final Act. 2–3; *see also* Ans. 7–8.

Appellant disagrees with this analysis referring "to the prior-submitted Declaration of Damon Getman, Ph.D." App. Br. 4; *see also* Reply Br. 1–2. One argument so presented is that when the Specification refers to a "patient" (*see* Appellant's Specification *generally*), it "is universally

understood to mean a human subject seeking or receiving medical care." App. Br. 5; Reply Br. 2; Decl. 2.

Appellant explains:

> In addition, as stated in MPEP § 2163(II)(A)(3)(a) "if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, ***even if every nuance of the claims is not explicitly described in the specification***, then the adequate description requirement is met. See, e.g., *Vas-Cath* [*Inc. v. Mahurkar*], 935 F.2d [1555,] 1563, 19 USPQ2d at 1116 [(Fed. Cir. 1991)]; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating 'the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient')."

Reply Br. 2–3; *see also* App. Br. 4. Appellant thus concludes, "a skilled artisan would have understood the inventor to be in possession of urethra sampling instruments and methods to be used on *human patients*." Reply Br. 3; *see also* App. Br. 4, 6.

The purpose of the written description requirement is to assure that the public receives sufficient knowledge of the patented technology, and to demonstrate that the patentee is in possession of the invention claimed. *See In re Skvorecz*, 580 F.3d 1262, 1269 (Fed. Cir. 2009). There is no dispute that Appellant's Specification is directed to swabbing a urethra of a "patient." *See, e.g.*, ¶¶ 13–16 and 22–25. The question that remains is whether the public has received sufficient knowledge to demonstrate that Appellant was in possession of the swabbing of a "human" patient, as presently claimed. We determine that it has.

For example, paragraph 2 of Appellant's Specification discusses the Background of the claimed subject matter stating that swabs are currently "used for the collection of specimens to test for sexually transmitted

diseases." *See also* Spec. ¶ 13. We understand that this is a matter that humans are particularly concerned with as is self-evident from a reading of both general and more specialized literature.[2] Thus, from a review of Appellant's Specification and the above guidance from our reviewing court, we agree with Appellant that it would have been reasonable for one skilled in the art to understand Appellant's discussion of swabbing a "patient" ("[t]he swab assembly 10 may be used for collecting cellular material that may be used to test for sexually transmitted diseases" (Spec. 13)) to encompass, or be directed to, a human patient.

Accordingly, and based on the above, the Examiner's repeated assertion that "patient" might also refer to non-human patients (*see* Non-Final Act. 2; Ans. 7), is not persuasive that Appellant lacked written description support for the claims as presented. We reverse the Examiner's rejection of independent claims 1, 8, and 13, and dependent claims 3 and 14, for "failing to comply with the written description requirement." Non-Final Act. 2.

The rejection of claims 1, 3, 8, 13, and 14 as unpatentable over Marshall, Sak, and Burg

Each independent claim, i.e., claims 1, 8, and 13, includes the limitation of a collection tip and a sheath, with this collection tip being configured to be compressed within the sheath. The Examiner primarily relies on the teachings of Marshall for disclosing "a collection tip (13)" and on Sak for teaching "wherein the collection tip is configured to be

[2] An Internet search conducted January 14, 2019, and using the terms "sexually transmitted diseases in humans" identified 16,200,000 results. A different search engine identified about 71,700,000 results.

compressed and positioned entirely within the sheath." Non-Final Act. 3–4. The Examiner reasons that it would have been obvious to combine the teachings of Marshall and Sak "to protect the collection tip from touching unwanted tissue until it is positioned at the collection site." Non-Final Act. 4 (referencing, e.g., Sak Figs. 7 and 8); Ans. 9. Appellant does not address the teachings of Burg and thus we need not address the Examiner's reliance on Burg for disclosing the recited notch. *See* Non-Final Act. 4–5.

Appellant addresses the compressibility of Marshall's tip 13 and also states that "[n]o insertion sheath is provided ***or needed*** with Marshall's solution." App. Br. 7. Appellant further addresses the fact that "the tip taught by Marshall is not compressible." Reply Br. 4 (referencing Marshall 2:7–8 stating that tip 13 is "relatively inflexible"). Marshall further states that the size of tip 13 is "preferably of about 3 mm, which is significantly smaller than the average diameter of the male or female urethra of about 6 mm." Marshall 2:34–37. Appellant argues that not only is "the tip taught by Marshall . . . not compressible" but that "a sheath for compressing the tip is not even necessary in the Marshall device" (Reply Br. 4) "***or needed***" (App. Br. 7).

Marshall clearly describes a tip that is "relatively inflexible" and whose size is already about half that of a "male or female urethra." Marshall 2:7–8, 2:34–37. The Examiner does not make clear why one skilled in the art would seek to compress Marshall's "relatively inflexible" tip when the size of Marshall's tip is already more than adequate for insertion into a urethra, as expressed in Marshall. Instead, the Examiner addresses a need to protect the tip from contamination. Non-Final Act. 4; Ans. 9. However, protecting a tip does not correlate to compressing a tip that is already

properly sized, and which has been described as being "relatively inflexible." Instead, it appears the Examiner gleaned the need for compression of the tip from Appellant's disclosure. *See* App. Br. 7; Reply Br. 3.

As is well-known, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). The Examiner's stated rationale lacks such articulated reasoning with rational underpinning concerning the compressible tip, and as such, is insufficient to support the legal conclusion of obviousness. We reverse the Examiner's rejection of independent claims 1, 8, and 13, and also the rejection of dependent claims 3 and 14, which are not separately argued.

DECISION

The Examiner's rejection of claims 1, 3, 8, 13, and 14 as failing to comply with the written description requirement is reversed.

The Examiner's art rejection of claims 1, 3, 8, 13, and 14 is reversed.

REVERSED