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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEVEN STREATFIELD GILL and PAUL DAVID FIELDER

Appeal 2018-006122
Application 14/581,549
Technology Center 3700

Before MICHAEL C. ASTORINO, PHILIP J. HOFFMANN, and TARA L. HUTCHINGS, *Administrative Patent Judges*.

HUTCHINGS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant[1] appeals under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 1–3 and 5–17. An oral hearing was held on February 6, 2020. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Our decision references Appellant's Appeal Brief ("Appeal Br.," filed Jan. 29, 2018), Reply Brief ("Reply Br.," filed May 25, 2018), and Declaration of Steven Streatfield Gill, filed October 29, 2017), and the Examiner's Answer ("Ans.," mailed April 2, 2018) and Final Office Action ("Final Act.," mailed Aug. 28, 2017). Appellant identifies Renishaw PLC as the real party in interest. Appeal Br. 1.

CLAIMED INVENTION

Appellant's claimed invention relates to a "percutaneous implant, especially neurological apparatus comprising a percutaneous access device suitable for use with an implanted intracranial catheter." Spec. ¶ 2.

Claims 1 and 16 are the independent claims on appeal. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. Apparatus for delivering a therapeutic agent to the central nervous system, comprising:
>
> at least two intracranial catheters; and
>
> a percutaneous access device, the percutaneous access device comprising a body having at least one extracorporeal surface and at least one subcutaneous surface, the body defining at least two ports for connection to said intracranial catheters, each port being accessible from the extracorporeal surface of the device, but being provided with a seal between the lumen of the port and the extracorporeal surface, each port separately passing through the body such that each intracranial catheter is separately accessible from the extracorporeal surface of the device.

REJECTIONS

Claims 1–3, 6, 8, 11, 12, 16, and 17 are rejected under 35 U.S.C. § 103(a) as unpatentable over Baudino (US 5,954,687, iss. Sept. 21, 1999), Brown (US 4,695,273, iss. Sept. 22, 1987), and Haarala (US 2003/0004520 A1, pub. Jan. 2, 2003).

Claim 5 is rejected under 35 U.S.C. § 103(a) as unpatentable over Baudino, Brown, Haarala, and Nussbaum (US 5,352,207, iss. Oct. 4, 1994).

Claim 7 is rejected under 35 U.S.C. § 103(a) as unpatentable over Baudino, Brown, Haarala, and Sommerich (US 2004/0243064 A1, pub. Dec. 2, 2004).

Claims 1–3, 5, 6, and 8–17 are rejected under 35 U.S.C. § 103(a) as obvious over Inman (US 4,578,063, iss. Mar. 25, 1986), Brown, and Haarala.

Claim 7 is rejected under 35 U.S.C. § 103(a) as obvious over Inman, Brown, Haarala, and Sommerich.

ANALYSIS

Obviousness Over Baudino, Brown, and Haarala

We are persuaded by Appellant's argument that the Examiner erred in rejecting claims 1 and 16 under 35 U.S.C. § 103(a) because Baudino does not disclose a percutaneous access device comprising a body having at least one extracorporeal surface and at least one subcutaneous surface, as recited by claim 1, and similarly recited in claim 16. The Examiner relies on Baudino for teaching a percutaneous access device. Final Act. 2 (citing Baudino, Fig. 2).

Baudino relates to a low profile access port for establishing fluid communication with the brain, such as for the administration of drugs. Baudino 1:5–9. Baudino teaches with reference to Figure 2, a burr hole ring 16 that is secured within a burr hole drilled into the skull. *Id.* at 1:52–55, 3: 49–51, 4:9–12. After insertion of burr hole ring 16 into the burr hole, threads or ridges 30 of the burr hole ring engage the skull at the inner sides of the drilled burr hole. *Id.* at 3:51–53. A septum 32 is placed in the top portion of burr hole ring 16 to isolate fluid reservoir 24 from the ambient environment. *Id.* at 3:61–63. A pharmaceutical can be delivered to a patient by inserting hypodermic needle 34 through septum 32 to inject the fluid agent. *Id.* at 3:63–67. Stylet 14 is inserted through septum 32 into central

connection tube 22 and, ultimately, catheter 12 for insertion into the patient's brain. *Id.* at 4:5–12.

To support the finding that Baudino teaches the claimed percutaneous device, the Examiner finds that Baudino at Figure 2 shows burr hole ring 16 having extracorporeal surface 18. *See* Final Act. 10; *see also* Ans. 2. Baudino's Figure 2 depicts a patient's skull with a burr hole drilled into the skull. Burr ring 16 is placed into the burr hole, threads 30 of ring 16 engage the skull, and upper flange 18 of ring 16 seats against the skull. However, Figure 2 does not depict a patient's skin or otherwise indicate that the burr ring has an extracorporeal surface, as required by claims 1 and 16.

Moreover, as pointed out by Appellant, upper flange 18, which is seated against the skull, is shown in all figures to be approximately half the thickness of the skull, suggesting that the flange has been designed to be subcutaneous. Appeal Br. 7 (citing Declaration 2–3); *see also* Reply Br. 2–3 (arguing that "the Baudino device simply is not thick enough to protrude through the skin, as explained in the Declaration"), Decl. 3 (declaring that Baudino's burr hole is approximately the same thickness as the skull; the upper flange of its burr hole ring is shown in all figures as approximately half the burr hole thickness; and the upper flange resting on the skull with half the height of the skull would not have sufficient height to emerge through the scalp, indicating that the flange has been designed to be low profile and subcutaneous).

The Examiner further reasons that Baudino's description of a septum isolating the reservoir from the ambient/external environment, indicates that the device would have an extracorporeal surface. Final Act. 10 (citing Baudino 3:61–63, 4:50–52). However, we agree with Appellant that the

Examiner does not adequately support the finding that the ambient environment described in Baudino is intended to refer to the environment outside of the patient's body (i.e., an extracorporeal environment) instead of outside the reservoir. *See* Appeal Br. 8; *see also* Reply Br. 4–5; Declaration 3–4. For example, the cited portions of Baudino do not describe a need to isolate the contents of the reservoir from the environment outside of the patient's skin, as opposed to isolating the contents from the environment immediately above the septum and external the reservoir, but below the skin.

The Examiner also reasons that the device has at least one extracorporeal surface because Baudino describes replacing a filter of the device, and that it would not follow to install the device under the skin where it would require repeatedly cutting the skin of the patient. Final Act. 10 (citing Baudino 6:10–15); *see also* Ans. 3. However, Baudino describes at column 6, lines 10–15 that the mounting member is detachable, allowing the filter assembly to be replaced when clogged or inoperable. Contrary to the Examiner's suggestion, there is no indication in the cited portion of Baudino that this service occurs frequently or that the mounting member is easy to replace. *See* Reply Br. 5; *see also* Baudino 6:10–15. Moreover, Appellant provides a declaration that subcutaneous devices are serviced and/or replaced periodically by cutting through skin. Appeal Br. 8 (citing Decl. 4); *see also* Decl. 4 (declaring that Baudino's filter replacement likely would occur infrequently, such as every few years, and that servicing and/or replacing implants every few years by cutting through the skin is a common neurosurgical practice). The Examiner does not address Appellant's argument.

We are not persuaded that the Examiner adequately supported the finding that Baudino is a percutaneous access device, as recited in claim 1, and similarly recited in claim 16. For at least this reason, we reverse the rejection of independent claims 1 and 16, and their dependent claims, under 35 U.S.C. § 103(a) as unpatentable over Baudino, Brown, and Haarala.

Obviousness Over Baudino, Brown, Haarala, and Nussbaum

The Examiner's rejection of dependent claim 5 under 35 U.S.C. § 103(a) as unpatentable over Baudino, Brown, Haarala, and Nussbaum does not cure the deficiency in the Examiner's rejection of independent claim 1 under 35 U.S.C. § 103(a) as unpatentable over Inman, Brown, and Haarala.

Therefore, we do not sustain the Examiner's rejection of claim 5 under 35 U.S.C. § 103(a) as unpatentable over Baudino, Brown, Haarala, and Nussbaum, for the same reasons set forth above with respect to the rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over Baudino, Brown, and Haarala.

Obviousness Over Baudino, Brown, Haarala, and Sommerich

The Examiner's rejection of dependent claim 7 under 35 U.S.C. § 103(a) as unpatentable over Baudino, Brown, Haarala, and Sommerich does not cure the deficiency in the Examiner's rejection of independent claim 1 under 35 U.S.C. § 103(a) as unpatentable over Baudino, Brown, and Haarala.

Therefore, we do not sustain the Examiner's rejection of claim 7 under 35 U.S.C. § 103(a) as unpatentable over Baudino, Brown, Haarala, and Sommerich, for the same reasons set forth above with respect to the rejection of independent claim 1 under 35 U.S.C. § 103(a) as unpatentable over Baudino, Brown, and Haarala.

Obviousness Over Inman, Brown, and Haarala

We are persuaded by Appellant's argument that the Examiner erred in rejecting independent claims 1 and 16 under 35 U.S.C. § 103(a), because Inman does not disclose at least two intracranial catheters, as recited in claim 1, or more than two intracranial catheters, as recited in claim 16. Appeal Br. 12–13, 17. The Examiner relies on Inman for disclosing an intracranial catheter, and Haarala for teaching a plurality of catheters attached to multiple ports. *See* Final Act. 6 (citing Inman, Fig. 4; Haarala ¶ 56, Figs. 3, 13).

Appellant argues that Inman discloses a venous catheter, not an intracranial catheter, as required by claims 1 and 16. Appeal Br. 12–13, 17. In response, the Examiner finds that "the limitation regarding the intracranial catheter is functional[,] and a catheter would need to be functional of such use." Ans. 6. The Examiner finds that the diameter of Inman's "barb indicates the diameter of the tube" (*id.* (citing Inman 10:55)), and that Inman teaches that such ports are beneficial for monitoring brain implants (*id.* (citing Inman 1:25). The Examiner finds that claims 1 and 16 do not recite any particular rate for dispensing fluid or dimensions for the catheter. *Id.* at 7. Therefore, the Examiner concludes that claims 1 and 16 require "only that a catheter be capable of intracranial placement" and finds that Inman at column 10, line 55 teaches a size that is capable of intracranial use. *Id.* (addressing claim 1), 9 (rejecting claim 16 on the same basis set forth with respect to claim 1).

As an initial matter we disagree with the Examiner's interpretation that the claimed intracranial catheter requires only a catheter capable of intracranial placement. Even if claims 1 and 16 do not recite dimensions of

the intracranial catheter or a rate for dispensing fluid, one of ordinary skill in the art would recognize that the claimed intracranial catheter is capable not only of intracranial placement but also of intracranial use.

Here, Appellant disputes the Examiner's finding that Inman's venous catheter is capable of being used as an intracranial catheter. Appeal Br. 12–13; *see also* Reply Br. 8–9, Decl. 7. Specifically, Appellant argues that a venous catheter delivers liters of fluid, such as hundreds of milliliters of drugs, to the bloodstream. Appeal Br. 12–13; *see also* Decl. 7. In contrast, a brain infusion dispenses small amounts of fluid over a period of time, such as 300 microliters over two hours. Appeal Br. 13; *see also* Decl. 7. Appellant contends that because a venous catheter delivers a much larger volume of drugs, its diameter is larger than an intracranial catheter. Appeal Br. 12–13. Thus, if one were to use this type of catheter in a neuro application, the catheter would be unable to dispense a precise but small amount of liquid due to the dead volume during dispensing. *See id.*; *see also* Declaration 12–13 (comparing the use of a venous catheter in a neuro application to using a garden hose to apply a drop of oil to a door hinge).

Appellant further supports this argument by pointing out that Appellant's Specification at paragraph 18 cites Gill[2] as an exemplary intracranial catheter. Gill describes that an external catheter of a neurosurgical catheter has an external diameter of no more than 1.0 millimeter, a preferred diameter of no more than 0.7 millimeter, a more preferred diameter of no more than 0.65 millimeter, and a most preferred diameter of no more than 0.5 millimeter. Gill 3–4.

[2] Gill (WO 2003/077785 A1, pub. Sept. 25, 2003).

The Examiner finds that column 10, line 55 of Inman indicates that Inman's venous catheter is sized for use as an intracranial catheter, asserting that the diameter of the barb indicates the diameter of the tube. Ans. 6–7. Yet, Inman at column 10, lines 53–57 provides that barbs 45 on connector 42 range from 0.1 inch to 0.6 inch, and provide a snap-in fit at the port. Inman further describes that the outer diameter of connector 42 is 0.2 inch to 0.5 inch. Inman 10:46–47. As pointed out by Appellant (Reply Br. 8), Inman's dimensions are equivalent to a metric range of 5.1 mm to 12.7 mm, which are much larger than the exemplary dimensions for an intracranial catheter as provided by reference to Gil in Appellant's Specification.

For at least this reason, we are persuaded that the Examiner erred in rejecting independent claims 1 and 16, and dependent claims 2, 3, 5, 6, 8–15, and 17 under 35 U.S.C § 103(a) as unpatentable over Inman, Brown, and Haarala.

Obviousness Over Inman, Brown, Haarala, and Sommerich

The Examiner's rejection of dependent claim 7 over Inman, Brown, Haarala, and Sommerich does not cure the deficiency in the Examiner's rejection of independent claim 1 under 35 U.S.C. § 103(a) as unpatentable over Inman, Brown, and Haarala.

Therefore, we do not sustain the Examiner's rejection of claim 7 under 35 U.S.C. § 103(a) as unpatentable over Inman, Brown, Haarala, and Sommerich, for the same reasons set forth above with respect to the rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over Inman, Brown, and Haarala.

CONCLUSION

In summary:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–3, 6, 8, 11, 12, 16, 17	103(a)	Baudino, Brown, Haarala		1–3, 6, 8, 11, 12, 16, 17
5	103(a)	Baudino, Brown, Haarala, Nussbaum		5
7	103(a)	Baudino, Brown, Haarala, Sommerich		7
1–3, 5, 6, 8–17	103(a)	Inman, Brown, Haarala		1–3, 5, 6, 8–17
7	103(a)	Inman, Brown, Haarala, Sommerich		7
Overall Outcome				1–3, 5–17

REVERSED