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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KELLY B. POWERS, JIM C. BEASLEY,
KEVIN W. SHEETZ, MATTHEW M. LOWE,
EDDIE K. BURNSIDE and JAY GERONDALE

Appeal 2016-008422
Application 14/171,364
Technology Center 3700

Before: STEVEN D.A. McCARTHY, BRETT C. MARTIN and ERIC C. JESCHKE, *Administrative Patent Judges*.

McCARTHY, Administrative Patent Judge.

DECISION ON APPEAL

STATEMENT OF THE CASE

The Appellants[1] appeal under 35 U.S.C. § 134(a) from the Examiner's decision finally rejecting claims 1–5 and 7–11 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Fago (US 2004/0024361 A1, publ. Feb. 5, 2004) and Tallarida (US 2003/0181878 A1, publ. Sept. 25, 2003); and of claims 6 and 12 under § 103(a) as being unpatentable over Fago, Tallarida

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[1] The Appellants identify C.R. Bard, Inc. as the real party in interest. We note that a "Notice of Change in Real Party-in-Interest Pursuant to 37 C.F.R. § 41.8," dated January 15, 2018, was filed in *Inter partes* Reexamination Control No. 95/002,089, saying that C.R. Bard, Inc., has become a wholly owned subsidiary of Becton, Dickinson and Company.

and Borchard (US 2004/0078000 A1, publ. Apr. 22, 2004). We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

Claims 1 and 7 are independent:

> 1. A method of power injecting a fluid through an access port, comprising:
>
> providing a power-injectable access port suitable for injecting contrast media therethrough at a rate of at least 1 milliliter per second, the access port including:
>
> a housing;
>
> a septum;
>
> a reservoir; and
>
> an outlet stem in fluid communication with the reservoir, the access port structured for accommodating a pressure developed within the reservoir of at least 35 psi;
>
> attaching a catheter to the outlet stem;
>
> implanting the power-injectable access port and catheter into a patient;
>
> inserting a distal end of a needle through the septum and into the reservoir; and
>
> injecting contrast media through the needle at a rate of at least one milliliter per second.
>
> 7. A method of power injecting a fluid through a power-injectable access port, comprising:
>
> inserting a distal end of a needle through a septum and into a reservoir of a power-injectable access port suitable for injecting contrast media therethrough at a rate of at least 1 milliliter per second, the access port structured for accommodating a pressure developed within the reservoir of at least 35 psi, the

> power-injectable access port including an outlet stem in fluid communication with the reservoir, the outlet stem attached to a catheter implanted into a patient along with the power-injectable access port; and
>
> injecting contrast media through the needle at a rate of at least one milliliter per second.

Fago describes an injector *20* for "deliver[ing] radiographic contrast media at a controlled flow rate and volume into a patient's vascular system for the purpose of obtaining enhanced diagnostic [x-ray] images." (Fago, paras. 16 & 47; *see also id.*, para. 56). Fago's injector *20* includes a powerhead *22*. The powerhead *22* includes a drive system *24* for extending a plunger drive ram *46* and a syringe plunger *74* through a cavity *70* of a syringe *28* mounted on the powerhead *22* to expel fluid from the syringe into a catheter leading to tissue of interest in the imaging process. (*See* Fago, paras. 48, 58 & 69; & Figs. 2 & 3). Fago indicates that the injector *20* is capable of generating a pressure as high as 250 psi in the syringe *28*; and that the plunger drive ram *46* and syringe plunger *74* are capable of expelling fluid from the syringe at a flow rate of 2.5 ml/sec. (*See* Fago, para. 89). Paragraph 56 of Fago teaches expelling fluid from the syringe *28* at a rate of 1 ml/sec to 6 ml/sec, at a maximum pressure limit of about 250 psi.

Fago taught that, as of its filing date:

> Many [then-]current power injectors [had] a maximum pressure limit in order to provide safety to the components of the power injector. This prevent[ed] the injector from being damaged by being subjected to forces greater than [the injector's components were] rated to withstand. These injectors also allow[ed] the operator to reduce the set maximum pressure limit to provide safety to a patient or other subject to be injected. For example, access ports [were] inserted into patients who need[ed] medication intravenously, but whose veins [could not] tolerate

> multiple needle sticks. Access ports that [were] implanted into patients [could not] tolerate many of the high pressures capable of being generated by these large injectors. High flow rates and pressures [could] cause the implanted catheter portion of the access port to break and require surgery to remove. For example, 100 psi [was] generally a threshold of pressure that a typical access port [was] able to withstand. However, a typical large [computed tomography ("CT")] injector [could] attain pressures during delivery of media of 300 psi at all flow rates. Thus, unless the pressure of such an injector [was] manually reduced, the access ports in a patient [could] become over-pressured and possibly fail. Limiting the pressure for the injection of fluid into an access port for a contrast study require[d] a technologist to reprogram the injector to reduce the pressure limit. If the technologist [forgot] to reset the limit to the higher setting once the application [had] been performed, the desired flow rate [might] not be achieved during injections for subsequent patients.

(Fago, para. 5). Fago addressed this problem by programming the injector *20* to automatically set the pressure within the syringe *28* based on the flow rate of liquid from the syringe (*see* Fago, paras. 26 & 47); and automatically slowing or halting the flow of fluid from the syringe if the pressure exceeds a predetermined limit (*see id.*, paras. 88 & 89).

As the Appellants correctly point out, Fago did not teach "providing a power-injectable access port suitable for injecting contrast media therethrough at a rate of at least 1 milliliter per second," or providing an "access port structured for accommodating a pressure developed within the reservoir of at least 35 psi," as recited in claim 1. Neither did Fago teach providing an "access port structured for accommodating a pressure developed within the reservoir of at least 35 psi," as recited in claim 7. (*See* Appeal Brief, dated Jan. 25, 2016 ("App. Br."), at 8–10). Instead, Fago taught that the pressures generated in an implanted access port by a power

injector communicating with the reservoir of the port typically exceeded the maximum pressures for which such access ports were rated.[2]

The Examiner has not shown that paragraph 56 of Fago teaches injecting a contrast medium into an implanted access port, as found in the last sentence on page 6 of the Examiner's Answer, mailed July 29, 2016 ("Ans"). For example, the teachings of paragraph 56 are consistent with injecting the contrast medium through a percutaneous central venous catheter.

Paragraph 5 of Fago taught a problem that might be addressed by "providing a power-injectable access port suitable for injecting contrast media therethrough at a rate of at least 1 milliliter per second," or by

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[2] In the event that the underlying application undergoes further prosecution in the wake of this Final Decision, we direct the Examiner's attention to Gebauer et al., *Contrast Media Power Injection Using Central Venous Port Catheters—Results of an In-Vitro Study*, 117 RÖFO—ADVANCES IN THE FIELD OF X-RAYS & IMAGING TECHNIQUES 1417 (Georg Thieme Verlag KG, Stuttgart, Germany, Oct. 2005). An English-language abstract of the article appearing, as of the date of this opinion, at https://www.ncbi.nlm.nih.gov/pubmed/16170712, describes the article as a study answering in the affirmative the question: "Are implanted central venous port catheters suitable for contrast media pressure (power) injection in computed tomography?" Tables 2 and 3, reproduced on page 9 and 10 of an English-language translation submitted in *Inter partes* Reexamination 95/002,089 as an attachment to an Information Disclosure Statement, dated February 7, 2013, list several examples of implantable port catheter systems having manufacturer rated pressures above 35 psi that were tested at flow rates of 2 ml/sec and higher. The article appears to pre-date each parent application listed in paragraph 1 of the underlying application, except for US Provisional Application 60/675,309. Although paragraph 45 of US Provisional Application 60/675,309 mentions power injection, it is not apparent that the port pressure and flow rate ranges recited in claims 1 and 7 appear in the provisional application.

providing an "access port structured for accommodating a pressure developed within the reservoir of at least 35 psi," as recited in claim 1. Nevertheless, as the Appellants point out, Fago teaches solving the problem by regulating the pressure of the fluid in the syringe *28*, as well as the flow rate of the fluid from the syringe, rather than by using a power-injectable access port. (*See* Fago, paras. 26, 47 & 87–89; *see also* App. Br. 8).

Tallarida does not remedy this deficiency. As depicted in Figures 2A and 2B, Tallarida describes an implantable access device *10* including a housing member *12*, a septum *16*, a reservoir *22* and an outlet stem *20*. (*See* Tallarida, para. 42). Tallarida addresses problems associated with known access devices having metallic or polymeric housings by providing the polymeric housing member *12* with a metallic cup member *14* and a molded top member *24* for improved durability. (*See* Tallarida, paras. 29, 31, 35 & 44). Tallarida does not describe the access device depicted in Figures 2A and 2B as power-injectable; provide a pressure rating or flow rate for the device; or address any problem relating to the use of the device for power injecting a contrast medium.

The Examiner concludes that:

> [it would have been obvious] to include the structure of the access port and the steps of implanting an access port as taught by Tallarida et al. since it was well known in the art that subcutaneous access ports are utilized to deliver fluids into the bloodstream of a patient and typically include a housing, septum, reservoir, and outlet stem.

(Final Office Action, mailed June 25, 2015 ("Final Act."), at 3, *citing* Tallarida, para. 12). The conclusion does not address the deficiencies in the teachings of Fago and Tallarida as applied to claims 1 and 7. We do not sustain the rejection of claims 1–5 and 7–11 under § 103(a) as being

unpatentable over Fago and Tallarida. Based on our holding, we do not address the Appellants' separate arguments regarding the dependent claims.

Borchard describes an implantable drug pump having a reservoir refillable through an access port 210. (*See* Borchard, para. 20 & 21). Borchard also describes a kit for supplying drug to the implantable access pump. (*See* Borchard, para. 24 & Fig. 10). The Examiner cites Borchard as disclosing "an identification feature separate from the power-injectable access port comprising visually perceptible information." (Final Act. 4 & 5, *citing* Borchard, para. 8). This teaching does not remedy the deficiencies in the combined teachings of Fago and Tallarida as applied to independent claims 1 and 7. We do not sustain the rejection of claims 6 and 12 under § 103(a) as being unpatentable over Fago, Tallarida and Borchard.

DECISION

We REVERSE the Examiner's decision rejecting claims 1–12.

REVERSED