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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SPENCER A. JONES, DAVID R. DEPOYSTER,
DAVID L. NICHOLS, CHRISTOPHER M. RICHARDSON, and
KELLI L. SHADA

Appeal 2019-002553
Application 14/790,386
Technology Center 3700

Before MICHELLE R. OSINSKI, JEREMY M. PLENZLER, and
GEORGE R. HOSKINS, *Administrative Patent Judges*.

HOSKINS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 1–8, 11–13, 22–28, 31, and 32 in this application. The Board has jurisdiction over the appeal under 35 U.S.C. § 6(b).

We AFFIRM.²

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as BVAD Technologies, LLC. Appeal Br. 3.

² On February 8, 2019, Appellant timely filed a Request for Oral Hearing, but then waived the oral hearing on July 30, 2019. Thus, we proceed to decide the appeal on the briefs, without a hearing. *See* 37 C.F.R. § 41.47.

CLAIMED SUBJECT MATTER

Claim 1 illustrates the claimed subject matter on appeal, and it recites:

1. A venous access device, comprising:
 - (a) a hub, comprising,
 - (i) a bifurcated connecting arm,
 - (ii) a blood sampling arm, connected to the bifurcated connecting arm,
 - (iii) a fluid transfer arm, connected to the bifurcated connecting arm,
 - (iv) a blood sampling channel, passing through the blood sampling arm and the bifurcated connecting arm, and
 - (v) a fluid transfer channel, passing through the fluid transfer arm and the bifurcated connecting arm, and
 - (b) a bifurcated cannula, coupled to the bifurcated connecting arm, comprising,
 - (i) a blood sampling lumen, having a blood sampling port,
 - (ii) a fluid transfer lumen, having a fluid transfer port, and
 - (iii) a dividing member, separating the blood sampling lumen from the fluid transfer lumen,
- wherein the blood sampling port is 15 mm to 20 mm proximal from the fluid transfer port,
the bifurcated cannula has a length of 20 to 75 millimeters,
the bifurcated cannula is a 17 to 24 gauge cannula,
the blood sampling channel is fluidly connected to the blood sampling lumen, and
the fluid transfer channel is fluidly connected to the fluid transfer lumen.

Appeal Br. 18 (Claims App.).

REJECTIONS ON APPEAL

Claims 1–6, 8, 31, and 32 are rejected under 35 U.S.C. § 103 as unpatentable over Ash (US 5,947,953, issued Sept. 7, 1999), Hamatake

Appeal 2019-002553
Application 14/790,386

(US 2006/0004325 A1, published Jan. 5, 2006), and Kamath
(US 8,364,231 B2, issued Jan. 9, 2013).

Claim 7 is rejected under 35 U.S.C. § 103 as unpatentable over Ash, Hamatake, Kamath, and Borden (US 2007/0078437 A1, published Apr. 5, 2007).

Claims 11–13 are rejected under 35 U.S.C. § 103 as unpatentable over Ash, Hamatake, Kamath, and Gaudiani (US 2008/0082136 A1, published Apr. 3, 2008).

Claims 22 and 24–27 are rejected under 35 U.S.C. § 103 as unpatentable over Ash, Hamatake, Kamath, and Helm (US 2012/0197204 A1, published Aug. 2, 2012).

Claims 23 and 28 are rejected under 35 U.S.C. § 103 as unpatentable over Ash, Hamatake, Kamath, Helm, Schwamm (US 2004/0127813 A1, published July 1, 2004), and Miller (US 2007/0084742 A1, published Apr. 19, 2007).

OPINION

A. *Obviousness Over Ash, Hamatake, and Kamath (Claims 1–6, 8, 31, and 32)*

Appellant argues claims 1–6, 8, 31, and 32 as one group, without separately arguing any one claim in the group. *See* Appeal Br. 7–17. Accordingly, we select claim 1 to decide the appeal as to this ground of rejection, with the other grouped claims standing or falling with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Whether Ash is Analogous Art

Appellant raises the threshold issue of whether Ash is analogous art. *See* Appeal Br. 13–14.

Only “analogous” prior art references may be used to support an obviousness determination. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (citing *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992)). A prior art reference is analogous to an application (1) if it is from the same field of endeavor as the inventor’s, regardless of the problem addressed, or (2) if the reference is not within the field of the inventor’s endeavor, it is nonetheless reasonably pertinent to the particular problem with which the inventor is involved. *Id.* (citations omitted). A reference is reasonably pertinent if it is one that, because of the matter with which it deals, would have logically commended itself to an inventor’s attention in considering the invention as a whole. *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379–80 (Fed. Cir. 2007).

Appellant argues the inventors’ field of endeavor is a “peripheral venous access device,” whereas Ash discloses a “central” venous access device. Appeal Br. 14. These represent different fields of endeavor, in Appellant’s view, because peripheral devices are used “routinely in nearly any doctor’s office or clinic” to “administer IV therapy or obtain blood samples,” whereas central devices are administered using a “surgical procedure” for “patients who have long term care needs,” such as “hemodialysis, perfusion, infusion, plasmapheresis and chemotherapy.” *Id.*

The Examiner responds that Appellant’s Specification “does not limit the field of endeavor to peripheral venous access devices,” and instead focuses on “the broad field of venous access devices capable of both fluid

delivery and blood sampling.” Ans. 16 (citing Spec. ¶ 28). The Examiner concludes Ash is from the same field of endeavor. *Id.* (citing Ash, 5:50–53).

We agree with the Examiner. Appellant’s Specification generally discusses “intravenous (IV) therapy to deliver or withdraw fluids,” which may involve “a peripheral venous catheter *or* a central venous catheter.” Spec. ¶¶ 1–2 (emphasis added). Appellant’s Specification does not limit the field of endeavor to one or the other type of intravenous delivery. *Id.*; *see also id.* ¶¶ 8–10 (“Summary” discussion), ¶¶ 28–29 (“The present invention is a venous access device that is capable of both transferring fluids and sampling blood intravenously from the same device simultaneously.”). Based on Appellant’s Specification, we conclude the inventors’ field of endeavor is intravenous access devices. Ash discloses such a device, and therefore falls within the inventors’ field of endeavor. *See* Ash, 5:15–24, 5:32–53.

Appellant additionally argues Ash “is not pertinent to the problem faced by the inventor[s],” which Appellant characterizes as “reducing needle sticks for routine blood testing and avoiding sample contamination.” Appeal Br. 14. Appellant contends Ash is concerned with the different problem of “moving large volumes of blood or fluid into or out of the body.” *Id.*

The Examiner responds that the inventors’ problem was the “need for a blood sampling device that eliminates repeated patient disturbances and painful needle sticks.” Ans. 17 (quoting Spec. ¶ 28). The Examiner determines Ash is reasonably pertinent to that problem, because Ash provides a venous access device that does not require multiple needle sticks or patient disturbances to exchange fluids within the patient’s venous system. *Id.*

We agree with the Examiner. Even if the problem addressed by the inventors is reducing needle sticks for blood testing and avoiding sample contamination, as set forth by Appellant, Ash's device is reasonably pertinent to the problem, because it provides for "chronic" catheterization wherein the catheter is secured to a subcutaneous area of the patient's body for extended use. Ash, 4:65–5:14 (Fig. 6), 9:13–31. Moreover, an additional problem addressed by the inventors was how to draw blood and deliver medicaments to the blood stream at the same time without contaminating the drawn blood with the medicament, which also is addressed by Ash's device. *See Spec.* ¶¶ 28–29; Ash, 5:15–19, 10:31–11:23.

For the foregoing reasons, we determine Ash is analogous art to the present application.

Prima Facie Obviousness Over Ash, Hamatake, and Kamath

The Examiner finds Ash's catheter assembly 10 has the structural configuration required by claim 1. That is, the Examiner finds Ash's assembly 10 has a hub (i.e., hub 24) having a blood sampling arm with a blood sampling channel, a fluid transfer arm with a fluid transfer channel, and a bifurcated connecting arm through which both channels pass. Final Act. 2–3. The Examiner finds Ash's assembly 10 also has a bifurcated cannula (i.e., cannulating portion 20) coupled to the hub's bifurcated connecting arm, and comprising first catheter 26 having a blood sampling lumen and port 76, and second catheter 30 comprising a fluid transfer lumen and port 80. *Id.*; *see also* Ash, Figs. 1 & 3, 9:38–46. Appellant does not challenge the foregoing findings, which we determine are supported by a

preponderance of the evidence. *See also* 37 C.F.R. § 41.37(c)(1)(iv) (arguments not included in Appeal Brief are waived).

The Examiner next determines Ash’s catheter assembly 10 is not disclosed to have dimensions falling within the ranges required by claim 1. Final Act. 3. That is, blood sampling port 76 and fluid transfer port 80 are not disclosed to be separated by 15–20 mm; the length of bifurcated cannula 20 is not disclosed to be 20–75 mm; and the gauge of bifurcated cannula 20 is not disclosed to be 17–24. *Id.*

The Examiner finds “Hamatake teaches the blood sampling port is 15 mm to 20 mm proximal from the fluid transfer port.” *Id.* (citing Hamatake ¶ 51, as disclosing a port separation of about 5–100 mm).³ The Examiner determines it would have been obvious to use Hamatake’s port separation in Ash’s bifurcated cannula 20, “so that each lumen is in independent fluid communication with the interior of a blood vessel” and to “decrease recirculation while maximizing flow rates.” *Id.* at 4 (paraphrasing Hamatake ¶ 51, Abstract).

The Examiner finds Kamath discloses a bifurcated cannula having a length of 20–75 mm, and a gauge of 17–24. *Id.* (citing Kamath, 34:23–36). The Examiner determines it would have been obvious “to have included the catheter length and gauge of Kamath in the venous access device of Ash to provide any of a variety of sizes and lengths for the desired application . . . as suggested by Kamath.” *Id.*

³ Here and elsewhere in this Decision, for ease of presentation, we have converted all distances to millimeters as specified in claim 1, understanding 1 inch equals 25.4 millimeters, and 1 centimeter equals 10 millimeters.

Appellant contends the Examiner's foregoing prima facie case for obviousness is deficient, because the proposed modifications would render Ash's device unsuitable for its intended purpose. Appeal Br. 8–10, 14–15. According to Appellant, Ash's intended purpose is to provide a *central* intravenous access device, to be used for hemodialysis, perfusion, infusion, plasmapheresis, and chemotherapy, so it needs to be long enough to cannulate “the central area” of the patient's body. *Id.* at 8–10 (citing Ash, 5:15–20, 5:42–46, 10:30–34). Appellant also contends Ash's ports need to be separated by a sufficient distance, and Ash's catheters need to have a large enough gauge, to “provide greater flow rates” and “move large volumes of blood” required by such procedures. *Id.* (citing Ash, 7:14–16, 10:51–56, 10:66–11:17, 11:49–55). Thus, Appellant concludes reducing Ash's 40 mm port separation to fall within the claimed range of 15–20 mm, reducing Ash's cannula length from 203 mm to fall within the claimed range of 20–75 mm, and reducing Ash's size from 13.5 French to the claimed range of 17–24 gauge, would render Ash's device unsuitable for its intended purpose. *Id.*

The Examiner answers that, while hemodialysis via the jugular vein is Ash's “preferred application,” Ash also indicates hemodialysis is merely exemplary, and other uses are possible. *See* Ans. 9–12, 18–19 (citing Ash, 5:15–31, 5:46–53). The Examiner also concludes that, while hemodialysis requires moving large volumes of blood, the evidence does not support Appellant's contention that the other procedures disclosed in Ash (i.e., perfusion, infusion, plasmapheresis, chemotherapy, and other medical applications) likewise require moving large volumes of blood or other fluids. *See id.* at 10–11, 18–19 (citing Ash, 5:50–53). Finally, the Examiner finds

“Ash does not clearly state that the device is a central line device or *must* be disposed within the central area of the body.” *Id.* at 11 (emphasis added). Thus, the Examiner’s view is that the proposed modifications of Ash’s device would not render it unsuitable for its intended purpose. *See id.* at 12.

Appellant replies that “[w]hile Ash . . . is not limited to its preferred embodiments, the preferred embodiments are evidence that the Examiner must consider.” Appeal Br. 14. Appellant contends the “general statements” in Ash cited by the Examiner “do not teach or suggest a peripheral device,” and must be read in context to refer to treatments that are similar to those specifically identified in Ash, all of which require removing large volumes of fluid. *Id.* at 13–14.

We agree with the Examiner’s position that the proposed modifications of Ash’s catheter assembly 10 would not render the device unsuitable for its intended purpose. Ash specifically contemplates that assembly 10 can be decreased in size, to be used in medical applications other than hemodialysis. Ash, 5:42–53. Ash also indicates its device can be adapted for use in blood vessels other than the jugular vein, such as femoral veins or subclavian veins. *Id.* at 5:15–24. A cannula length approaching 75 millimeters (the upper end of Appellant’s claimed range) would seem to be appropriate to cannulate the femoral vein or the subclavian vein, or other veins close to those veins. *See also* Kamath, 34:9–30 (catheters designed to measure analytes found in a patient’s blood stream by accessing the circulatory system may advantageously be 19.1–50.8 mm long). Further, Appellant does not cite evidence to support the contention that the perfusion, infusion, plasmapheresis, and chemotherapy procedures identified by Ash (Ash, 5:15–19) require moving the same large volumes of blood or other

fluids that hemodialysis requires. Thus, the evidence does not support Appellant's contention that Ash's device needs to be larger than claimed to perform all of its intended uses.

Appellant does not otherwise dispute the Examiner's prima facie case for obviousness, which we determine provides a rational underpinning for the proposed obviousness, and is supported by a preponderance of the evidence, as set forth above. *See, e.g., In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007); *see also* 37 C.F.R. § 41.37(c)(1)(iv). Thus, we agree with the Examiner's conclusion that claim 1 is prima facie unpatentable over Ash, Hamatake, and Kamath.

Objective Indicators of Nonobviousness

Appellant next contends objective indicators — namely, superior and unexpected results, long felt need, and skepticism by experts — establish nonobviousness of the claimed invention. *See* Appeal Br. 10–13, 15–16; *In re Sullivan*, 498 F.3d 1345, 1351 (Fed. Cir. 2007).

For superior and unexpected results, Appellant contends Ash, Hamatake, and Kamath do not “describe simultaneously delivering fluids and sampling blood, while avoiding contamination of the blood sample.” Appeal Br. 10. We disagree. Hamatake discloses such a device. *See* Hamatake, Abstract (a multi-lumen catheter with “staggered lumen openings along the axial length of the catheter *may decrease recirculation while maximizing flow rates*”), ¶ 51 (Figure 1 illustrates three lumen openings 12, 14, 16, which “are staggered along the length of the catheter,” “so that *each of the lumens is in independent fluid communication with the interior of a*

blood vessel” (emphases added)), ¶ 4 (two lumens respectively remove and return blood, and third lumen introduces medications).

Appellant further relies on test results described in the “Jones Declaration,” which we understand refers to the Declaration of Spencer Jones (a named inventor in the present application), signed on February 27, 2018 and filed with the Office on March 20, 2018. Appeal Br. 10–11. Viewed in a light most favorable to Appellant, the Jones Declaration establishes that separating two ports by at least 15 mm, as recited in claim 1, will successfully prevent fluid expelled by the fluid transfer port from reaching the blood sampling port when placed in a peripheral vein. *See* Jones Decl. ¶¶ 6–13.

However, the Jones Declaration does not establish that a minimum separation of 15 mm was either surprising or unexpected in preventing the fluid expelled by the fluid transfer port from reaching the blood sampling port. As a general rule, when “the difference between the claimed invention and the prior art is some range or other variable within the claims . . . the applicant must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range.” *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (emphasis provided by Court); *see In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991) (alleged unexpected results must be shown to be unexpected compared with the closest prior art). Here, the closest prior art range is found in Hamatake, which discloses a minimum port separation in the range of 5–25 mm to ensure that “each of the lumens is in *independent* fluid communication with the interior of a blood vessel.” Hamatake ¶ 51 (emphasis added).

The presently claimed minimum port separation of 15 mm falls squarely within the middle of Hamatake’s disclosed range of 5–25 mm as a minimum port separation to ensure independent fluid communication between two ports within a blood vessel. Thus, in light of Hamatake’s disclosure, there is nothing surprising or unexpected about a 15 mm minimum separation preventing contamination of a blood sampling port by fluid expelled from a fluid transfer port. *See In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997) (establishing an expected result requires “show[ing] that the claimed invention exhibits some *superior property or advantage* that a person of ordinary skill in the relevant art *would have found surprising or unexpected*”) (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995)) (emphasis added). For example, the Jones Declaration does not provide any comparative test results showing that the minimum 15 mm separation represents superior results versus other port separation distances disclosed by Hamatake. *See Geisler*, 116 F.3d at 1469–70 (“it is well settled that unexpected results must be established by factual evidence,” not “[m]ere argument or conclusory statements”) (citations omitted). Thus, the Jones Declaration is not persuasive of superior or unexpected results as to the claimed minimum port separation of 15 mm.

We appreciate that the tests discussed in the Jones Declaration simulated accessing “peripheral veins in the human forearm” (Jones Decl. ¶ 7), whereas Hamatake appears to focus on accessing a “central” vein (Hamatake ¶ 6) not a peripheral vein. However, neither the Jones Declaration nor Appellant’s argument *compares* the respective blood flows of a peripheral vein versus a central vein, to establish that a minimum port

separation to prevent cross-contamination may be expected to be materially different between those two environments.

Concerning the claimed maximum port separation of 20 mm, Appellant's counsel argues that if the ports were separated by "significantly more than 20 mm, then the overall length of the cannula must be longer" than the claimed maximum of 75 mm to remain suitable for peripheral use. Appeal Br. 11. This contention is unsupported by evidence. *See id.* For example, the Jones Declaration is silent concerning the recited maximum port separation of 20 mm. Further, what happens with separations that are "significantly more" than the recited maximum of 20 mm (*id.*) is irrelevant to any criticality of 20 mm. Thus, Appellant's argument is not persuasive of superior or unexpected results as to the claimed maximum port separation of 20 mm.

For long felt need and expert skepticism, Appellant relies on a prior art publication: *WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy* (World Health Organization, ©2010) ("the WHO Guidelines"). Appeal Br. 12–13. Appellant contends the WHO Guidelines "recognized the various risks associated with each needle stick," and therefore demonstrates "a long-felt need for a device that reduces the number of needle sticks and allows hospital staff to obtain blood samples quickly, easily, and painless[ly] for the patients." *Id.* at 12. This alleged need was not solved by central line devices such as Ash and Hamatake, according to Appellant, because "these devices carry a risk of inaccurate laboratory

results and contamination.” *Id.* (citing WHO Guidelines, “pg. 14”).⁴

Appellant further contends the Jones Declaration establishes “that drawing a blood sample at the same insertion point as a fluid delivery lumen would not solve the problem, as the risk of diluting or contaminating the blood sample was believed to be too great.” *Id.* (citing Jones Decl. ¶ 16). Appellant also cites the WHO Guidelines as “demonstrat[ing] skepticism by experts regarding the use of a single venous access device for blood sampling and fluid transport at the same incision point” to achieve accurate results. *Id.* at 13 (citing WHO Guidelines § 2.2.3, Step 3, “*Hospitalized patients*”).

We determine the WHO Guidelines and the Jones Declaration do not support any long-felt need, or expert skepticism, in reducing the Ash multi-lumen catheter to a size that is appropriate for use in blood vessels smaller than the jugular vein. The cited WHO Guideline Section 2.2.3 concerns the use of “a needle and syringe” as “a single-use device for blood sampling drawing,” *not* a multi-lumen catheter such as disclosed in Ash. *See* WHO Guidelines, § 2.2.3, Table 2.2; *see also id.* at Step 1 (assembled equipment includes “an assortment of blood-sampling devices (safety-engineered devices or needles and syringes . . .)”). Thus, the WHO Guidelines’ warning not to “take blood from an existing peripheral venous access site because this may give false results” applies to repeated needle access, not to the prolonged access provided by a single incision to insert Ash’s catheter.

⁴ Appellant entered the WHO Guidelines into the record via an IDS filed on August 29, 2016. This copy of the reference lacks page numbering, so we have been unable to discern the exact disclosure on “pg. 14” that Appellant is citing here. We suspect it is § 2.2.3, Step 3, “*Hospitalized patients*.”

The WHO Guidelines also indicate “specimens from central lines carry a risk of contamination or erroneous laboratory test results.” *Id.* § 2.2.3, Step 3, “*Hospitalized patients.*” However, as the Examiner points out, the WHO Guidelines nonetheless contemplate using “an in-dwelling venous device,” and “[n]ursing staff and physicians may access central venous lines for specimens following protocols.” *Id.*; Ans. 14. That is, according to the WHO Guidelines, in-dwelling venous access devices may be used if protocols are followed to reduce the risk of contamination and erroneous laboratory test results. The only need or skepticism that might be established by the WHO Guidelines is whether one might be able to design an in-dwelling venous access device that reduces the risk of contamination and erroneous laboratory test results, such that safety protocols might be eliminated or made easier. There is no suggestion in the present record, however, that reducing the size of Ash’s catheter so that it may access a peripheral vein rather than a central vein would reduce the risk of contamination that would be present in *any* in-dwelling, multi-lumen catheter. Further, as discussed in detail above, Hamatake establishes how to avoid the risk of erroneous laboratory test results resulting from cross-contamination in a multi-lumen catheter.

In summary, we conclude the Jones Declaration provides very little evidence of superior or unexpected results. Further, the WHO Guidelines do not establish any long-felt need or expert skepticism in relation to multi-lumen catheters such as recited in claim 1. Accordingly, having fully considered Appellant’s evidence of nonobviousness, including the arguments pertaining to superior and unexpected results, long felt need, and skepticism by experts, and weighing all of the evidence anew, we agree with

the Examiner that the evidence of obviousness, on balance, outweighs the evidence of nonobviousness.

Conclusion

We determine a preponderance of the evidence supports the Examiner's rejection of claims 1–6, 8, 31, and 32 as obvious over Ash, Hamatake, and Kamath.

B. Obviousness over Ash, Hamatake, Kamath, and one or more of Borden, Gaudiani, Helm, Schwamm, and Miller (Claims 7, 11–13, and 22–28)

Appellant does not present further argument against the rejections of claims 7, 11–13, and 22–28 as obvious over Ash, Hamatake, Kamath, and one or more of Borden, Gaudiani, Helm, Schwamm, and Miller. *See* Appeal Br. 7. For the reasons provided above, we sustain these rejections. *See* 37 C.F.R. § 41.37(c)(1)(iv).

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	References / Basis	Affirmed	Reversed
1–6, 8, 31, 32	103	Ash, Hamatake, Kamath	1–6, 8, 31, 32	
7	103	Ash, Hamatake, Kamath, Borden	7	
11–13	103	Ash, Hamatake, Kamath, Gaudiani	11–13	
22, 24–27	103	Ash, Hamatake, Kamath, Helm	22, 24–27	
23, 28	103	Ash, Hamatake, Kamath, Helm, Schwamm, Miller	23, 28	
Overall Outcome			1–8, 11–13, 22–28, 31, 32	

Appeal 2019-002553
Application 14/790,386

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED