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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,269	02/17/2004	Keith M. Grispo	50319-00139	2232
25231	7590	11/07/2013	EXAMINER	
MARSH, FISCHMANN & BREYFOGLE LLP 8055 East Tufts Avenue Suite 450 Denver, CO 80237			GILBERT, ANDREW M	
			ART UNIT	PAPER NUMBER
			3767	
			NOTIFICATION DATE	DELIVERY MODE
			11/07/2013	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KEITH M. GRISPO

Appeal 2011-012184
Application 10/780,269
Technology Center 3700

Before ERIC GRIMES, LORA M. GREEN, and ZHENYU YANG,
Administrative Patent Judges.

YANG, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal¹ under 35 U.S.C. § 134 involving claims to methods for purging air from dual head injectors. The Examiner rejected claims 57, 58, and 68-80 as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

¹ Appellant identifies Mallinckrodt Inc. as the Real Party in Interest. (App. Br. 1.)

STATEMENT OF THE CASE

Claims 57, 58, and 68-80 are rejected and on appeal. They are directed to methods of using dual head injectors, and specifically, of purging air from such injectors. The Examiner rejected the claims under 35 U.S.C. § 103(a) as obvious over the combination of Emig² and Stellant.³

Claims 57 and 71 are independent claims. Claim 57 is representative of the subject matter on appeal. It reads:

57. A method of using a dual head injector, the method comprising:
mounting a first syringe to the injector;
mounting a second syringe to the injector;
coupling a first section of Y-tubing to the first syringe;
coupling a second section of the Y-tubing to the second syringe . . . ;

initiating a purging operation . . . wherein the first syringe comprises contrast media prior to the initiation of the purging operation, wherein the second syringe comprises saline prior to the initiation of the purging operation, and wherein the purging operation comprises:

advancing a first plunger drive ram of the injector to move a plunger of the first syringe to a first predetermined stop point where the plunger of the first syringe stops, wherein the advancing of the first plunger drive ram purges air from the first syringe and the first section of Y-tubing and fills the first section of the Y-tubing with contrast media from the first syringe . . . ; and

advancing a second plunger drive ram of the injector to move a plunger of the second syringe to a second predetermined stop point where the plunger of the second syringe stops, wherein the advancing of the second plunger

² Emig et al., U.S. Patent No. 6,471,674 B1, issued on Oct. 29, 2002.

³ Medrad, Inc., STELLANT CT INJECTION SYSTEM, Operation Manual Catalog #SOM 700 EN (2003).

drive ram purges air from the second syringe, the second section of the Y-tubing, the intersection of the first, second, and third sections of the Y-tubing, and the third section of the Y-tubing, wherein *the advancing of the first plunger drive ram occurs before the advancing of the second plunger drive ram*, and wherein the advancing of the second plunger drive ram comprises filling each of the second and third sections of the Y-tubing with saline from the second syringe; and
initiating an injection procedure

(Emphasis added.)

DISCUSSION

The only issue Appellant raises on appeal is whether the combination of Emig and Stellant would render the claimed invention obvious, even though neither reference explicitly discloses the sequence of the steps of advancing the two plunger drive rams as recited in the claims.

In rejecting claim 57, the Examiner found that Emig and Stellant disclose all the limitations except the sequence of advancing the two plunger drive rams. (Final Rej. 4, Ans. 6.) Citing column 6, lines 6-19 of Emig, the Examiner acknowledged that “it is not clear if Emig et al in view of Stellant explicitly disclose wherein the advancing of the first plunger drive ram occurs before the advancing of the second plunger drive ram.” (Final Rej. 4; Ans. 6.) Nevertheless, according to the Examiner,

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the purge protocol as taught by Emig et al with [the advancing of] the first plunger drive ram occurring before the advancing of the second plunger drive ram since changes in sequence are *prima facie* obvious in the absence of new or unexpected results (See MPEP 2144.04(IV)(C)). Having the first plunger drive ram

advancing before the second plunger drive ram does not provide a new or unexpected result in this case.

(Final Rej. 4-5; Ans. 6-7.)

Appellant argues that the Examiner erred in relying upon the presumption that “there are only two options for undertaking a purging operation: 1) a saline push followed by a contrast push; or 2) a contrast push followed by a saline push.” (App. Br. 11.) According to Appellant, “[a] purging operation could be configured in any appropriate manner, for instance one or more saline pushes, one or more contrast pushes, and in any combination (e.g., a saline push, followed by a contrast push, followed by another saline push).” (*Id.*) Appellant asserts that “[b]ased upon the vast option set for configuring a purging operation (which plunger drive ram to move at what time, and for how long), one skilled in the art simply would not be motivated to modify the teachings of Emig and/or Stellant OMC in any manner that would [yield] Appellant’s invention of claim 57.”⁴ (*Id.* at 12.)

A preponderance of the evidence supports the Examiner’s position that the claimed two-step purging operation, i.e., “push the contrast first followed by a saline push,” would have been obvious. (Ans. 10.) This is so even if, as Appellant would like us to find, there are more than two purging

⁴ At one point, Appellant argues that “Emig could be interpreted to define a purging operation that uses a saline prime, followed by a contrast prime. This is the exact opposite of the purging sequence set forth in claim 57” (App. Br. 9.) Upon reviewing Emig, we find no merit in this assertion. Indeed, a few pages later, in the same brief, Appellant concedes that “Emig does not explicitly disclose any sequence at all for the saline prime and contrast prime addressed therein.” (*Id.* at 13.)

sequences because as the Examiner correctly pointed out, “changes in sequence are *prima facie* obvious in the absence of new or unexpected results.” (Final Rej. 5; Ans. 7.)

Appellant faults the Examiner for relying on MPEP § 2144.04(IV)(C) to support the obviousness rejection. (App. Br. 12-13.) Appellant first argues that because he has demonstrated the criticality of the sequence in the purging operation, “reliance by the Examiner on the rationale of MPEP § 2144.04(IV)(C) is inappropriate.” (*Id.* at 12.) According to Appellant:

[T]he order of the advancement of the first and second syringe plunger drivers for a purging operation in accordance with claim 57 has been the focus of prosecution. Moreover, such a specific order reduces the waste of relatively expensive contrast, purges air prior to injection, and does so in what is in effect a simple two-step process (i.e., two syringe plunger drive ram movements).

(*Id.*)

Appellant has not pointed to any disclosure in the Specification, and we find none, that support this argument of criticality. (*See* Ans. 10-11 (stating that Appellant “does not mention ‘waste,’ ‘expense,’ or ‘simple’ in the specification as originally filed. Simply put, the Appellant lacks support for the purported criticality in the originally filed specification”). The Examiner is also correct in the observation that Emig “discloses the exact reasoning and criticality” for the air purging steps. (*Id.* at 11.) Indeed, Emig teaches “priming” of the fluid delivery path “to remove air from the fluid path and minimize wastage of contrast medium.” (Emig, col. 6, ll. 9-11.) Appellant has not provided any persuasive reasoning or credible evidence that the claimed invention achieves any advantage over, or even any result different from, Emig. *See In re Hampel*, 162 F.2d 483, 485 (CCPA 1947)

(upholding affirmance of obviousness rejection because “[t]here is nothing in the instant record which indicates that the particular order of steps produces results differing in any way from those which would be brought about if another order of steps were followed”).

Noting that the heading of the MPEP section is “Changes in Sequence of Adding Ingredients,” Appellant also contends that the legal precedent cited therein “on its face is inapplicable to claim 57.” (App. Br. 13.) We find Appellant’s argument unpersuasive. As the Examiner correctly pointed out, “the cases cited in 2144.04(IV)(c) are directed to processes and the obviousness of ordering of the known steps within that process.” (Ans. 11.) For example, in *Ex parte Rubin*, the claims were directed to a method of forming a laminated sheet requiring first impregnating the sheet with a thermosetting material and then coating it with a metallic film. 128 USPQ 440, 441 (BPAI 1959). The examiner decided that the prior art reference disclosing a process of making a laminated sheet with the two steps reversed rendered the claims prima facie obvious. *Id.* Because “no unexpected result is obtained by reversing the order of steps,” the Board of Patent Appeals and Interferences affirmed the obviousness rejection. *Id.* at 442. *See also In re Burhans*, 154 F.2d 690, 692 (CCPA 1946) (affirming obviousness rejection “in the absence of any proof in the record that the order of performing the steps produces any new and unexpected results”).

Similarly in this case, Appellant points to no evidence in the record showing that the claimed order of steps produces results differing in any way from those which would be brought about if another order of steps were

followed. Absent such new and unexpected results, we affirm the Examiner's rejection of claim 57.⁵ Claims 58 and 68-70 fall with claim 57.

Appellant argues that the deficiency of Emig in view of Stellant is also applicable to claim 71. (App. Br. 16.) This argument is not persuasive as we found no deficiency in the combination of Emig and Stellant. Thus, we affirm the Examiner's rejection of claim 71 for the same reason discussed above. Claims 72-80 fall with claim 71.

SUMMARY

We affirm the rejections on appeal.

TIME PERIOD FOR RESPONSE

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

AFFIRMED

cdc

⁵ Appellant also contends that the Examiner's other rationales supporting the obviousness rejection are flawed. (*See* App. Br. 13-15.) We do not address those arguments as we affirm based on the Examiner's first rationale.