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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JEFF BAKER, MARK BUNKER, and PAUL VAN DER POL

Appeal 2018-007364
Application 14/193,766
Technology Center 3700

Before MICHAEL J. FITZPATRICK, WILLIAM A. CAPP, and JILL D. HILL, *Administrative Patent Judges.*

HILL, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 2, 4, 5, 7–13, 15, 16, and 18–23. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

[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 the assignee Promising Ground, LLC. Appeal Br. 1.

BACKGROUND

Independent claims 1, 11, and 22 are pending. Claim 1, reproduced below, illustrates the claimed subject matter:

> 1. A container for storing a medicament and an injection member in a sterile condition until injection, the container comprising:
>
> a first housing defining a chamber in which a sterile medicament is contained, the first housing comprising a flange;
>
> a second housing, wherein the first housing is movable relative to the second housing, the second housing comprising a shoulder that overlaps with the flange;
>
> an injection member associated with a lower portion of the first housing;
>
> a first contaminant barrier disposed at a lower portion of the second housing;
>
> a second contaminant barrier between the shoulder and flange to prevent contaminants from entering the second housing, such that the first contaminant barrier, the second contaminant barrier, and the second housing are configured to seal the second housing to maintain sterility of the injection member until the injection member traverses the first housing during an injection, and to prevent contact with the injection member prior to the injection and post injection;
>
> a spring disposed between the first and second housings; and
>
> wherein when the first housing moves relative to the second housing in a first direction to deliver the medicament, the flange moves away from the shoulder, the spring is biased and the injection member traverses the first contaminant barrier and extends from the second housing, and when the first housing moves relative to the second housing in a second direction the injection member is retracted into the second housing to prevent an unintentional contact with the injection member, such that sterility of the medicament is maintained until the medicament is delivered, and wherein movement of the first housing relative to the second housing in the first direction occurs before the medicament is delivered.

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Cooper	US 4,568,336	Feb. 4, 1986
Jennings	US 4,643,200	Feb. 17, 1987
Fox	US 4,695,274	Sep. 22, 1987
Erez	US 5,578,014	Nov. 26, 1996
Hjertman	US 5,873,856	Feb. 23, 1999
Wien	US 6,537,257 B1	Mar. 25, 2003

REJECTIONS

I. Claims 1, 2, 4, 5, 7–10, and 22 stand rejected under 35 U.S.C. 103(a) as unpatentable over Fox, Hjertman, Cooper, Wien, and Jennings. Final Act. 2–3.

II. Claim 11–13, 15, 16, 18–21, and 23 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Fox, Hjertman, Cooper, Wien, Jennings, and Erez. Final Act. 12.

ANALYSIS

Rejection I – Claims 1, 2, 4, 5, 7–10, and 22

The Examiner finds that Fox (Figure 7) discloses a container for storing a medicament and an injection member 28, the container comprising: (1) a first housing 21' with a medicament chamber and a flange 63; and (2) second housing 22' with a shoulder 42 that overlaps the first housing's flange 63. Final Act. 3. The Examiner also finds that Fox's first housing 21' is movable relative to its second housing 22'. *Id*. The

Examiner then finds that Fox's injection member 28 is "associated with a lower portion of the first housing," and a first containment barrier 33 is "disposed at a lower portion of the second housing." *Id*. The Examiner finds that Fox's first housing moves relative to its second housing (1) in a first direction to deliver medicament, with the injection member 28 traversing the first contaminant barrier 33 to extend from the second housing, and (2) in a second direction to retract the injection member 28 into the second housing to prevent unintentional contact. *Id*. According to the Examiner, movement of the first housing relative to the second housing in the first direction occurs before the medicament is delivered. *Id.* at 3–4.

The Examiner finds that Fox fails to disclose the claimed spring, but finds this disclosure in Hjertman's biasing spring 50 between its first housing 10, 24 and second housing 30. *Id.* at 4. The Examiner concludes that it would have been obvious to employ Hjertman's spring 50 between Fox's first and second housings 21', 22' "to ensure that the needle becomes covered after use while reducing user error by making such covering automatic." *Id*.

The Examiner additionally finds that Cooper discloses a sterile medicament that would be obvious to employ in Fox to "prevent infection associated with containment medicaments." *Id.* at 5. The Examiner then finds that: (1) Wien discloses movable housings 10, 21 "configured to cover an injection needle" 12, and the importance of a sealed protective guard (distal seal 24 shown in Figure 6) to seal the needle in a fluid tight container; and (2) Jennings discloses movable housings 10, 22 with a seal 13 at a proximal opening between the housings. *Id.* at 5–6. The Examiner concludes that it would have been obvious to provide Fox with a second

contaminant barrier between the first and second housing, as disclosed by Jennings's seal 13, to ensure that Fox's housings form a sealed chamber for its needle "as is described as being beneficial by Wein." *Id.* at 6. The Examiner proposes multiple locations for placement of a second containment barrier in Fox, contending that "the precise location of the second contaminant barrier on the head/flange of the modified device of Fox is a product of obvious design choice." *Id.* at 11.

Rejection I – Claims 1, 2, 4, 5, 7–10, and 22

Appellant argues claims 1, 2, 4, 5, 7–10, and 22 as a group. Appeal Br. 5. We select claim 1 as representative. Claims 2, 4, 5, 7–10, and 22 stand or fall with claim 1.

Impermissible Hindsight

Appellant argues that the Examiner provides no "motivation or suggestion leading a person of ordinary skill in the art [] to combine Fox with Hjertman in the manner" proposed, and that "the only basis to make such a modification would be as a result of impermissible hi[nd]sight reasoning." Appeal Br. 7.

Appellant does not directly address the Examiner's explicitly stated reason for combining Fox and Hjertman (*see* Final Act. 4). In the Answer, the Examiner again explains that it would have been obvious to provide a spring between Fox's first and second housings "to permit automatic re-extension of the needle shield," and a skilled artisan "would reasonably recognize and appreciate that such automatic shield extension is desirable as it serves to limit user error by making covering automatic thereby eliminating the risk of inattentive users forgetting to manually re-extend the

shield and accidentally contaminating themselves with [a] used needle." Ans. 4, 7 (citing Hjertman 1:17-23, 3:19–21). The Examiner further responds that "automating a manual activity requires only routine and customary skill in the art." *Id.* at 5 (citing *In re Venner*, 262 F.2d 91, 95 (CCPA 1958)). The Examiner then notes that any judgment on obviousness is necessarily a reconstruction based on hindsight; "[b]ut so long as it takes into account only knowledge which was within the level of ordinary skill . . ., and does not include knowledge gleaned only from the applicant's disclosure, such [] reconstruction is proper." *Id.* at 7 (citing *In re McLaughlin*, 443 F.2d 1392 (CCPA 1971)).

We are not persuaded by Appellant's argument that the Examiner failed to provide a motivation to combine Fox with Hjertman in the manner proposed, because Appellant has not addressed the Examiner's stated reasoning and explained why it lacks a rational basis. Further, it is true that automating a manual activity has been determined to require only routine and customary skill in the art, and a conclusion of obvious is proper so long as it takes into account only knowledge which was within the level of ordinary skill and does not include knowledge gleaned only from the Appellant's disclosure. Certain additional arguments related to the Examiner's reasoning are addressed below.

Interfere with Functionality

Appellant also argues that including Hjertman's spring in Fox as proposed by the Examiner "would inte[r]fere with the functionality of Fox." Appeal Br. 7. According to Appellant, Fox is direct to one-handed self-injection with manual safety jacket retraction, and placing a biasing spring in Fox as proposed by the Examiner would cause the spring resistance to work

against manual retraction of the safety jacket, requiring "a user to maintain a two-handed grip." *Id*.

The Examiner responds that Appellant's argument relies on an embodiment of Fox (Figure 6) with rotation, not the embodiment of Fox (Figure 7) with no rotation used in the Examiner's proposed combination. Ans. 8. Appellant counters that putting Hjertman's spring into the embodiment of Fox's Figure 7 would "provide significant resistance" on proximal movement of the sleeve 22'. Reply Br. 2.

The Examiner argues that Hjertman describes how the modified Fox device would be understood to be operated for single-handed operation – "as the distal end of the second housing/shield is pressed against the skin, a downward force" is applied to "the first housing by a shield overcoming the spring bias to permit extension of the needle." Ans. 9–10 (citing Hjertman (Abstract, 2:64–67, 3:11–21). "After injection the downward force is released thereby allowing the shield to automatically extend over the sharpened distal tip", which would permit a "one-handed operation procedure and . . . automatic re-extension of the shield to ensure that a user is not exposed to the sharpened distal end of the needle accidentally." *Id.* at 10.

The Examiner has the better argument. Hjertman's spring is not specifically disclosed to require a large amount of force to overcome its bias to expose the needle. In addition to Hjertman teaching how to single handedly operate a spring biased injection device, "[a] person of ordinary skill in the art is also a person of ordinary creativity, not an automaton" and, "in many cases . . . will be able to fit the teachings of multiple patents together like pieces of a puzzle." *KSR Int'l Co. v. Teleflex Inc.*, 550

U.S. 398, 420–21 (2007). We simply are not persuaded that a skilled artisan would be unable to employ Hjertman's spring in Fox's housings and maintain Fox's one-handed operation.

Appellant further replies that the additional resistance against Fox's shield 22' created by utilizing the spring of Hjertman "would cause the medicament in Fox to be delivered from the needle 28 prior to penetration of the needle 28 through the end cap for injection causing the medicament in Fox to spill into the pocket 32." Reply Br. 2–3. Consequently, Appellant argues, in the modified Fox device, it would not be possible to move the first housing relative to the second housing in the first direction "before the medicament is delivered" as required by claim 1. *Id.* at 3. Because this argument is raised for the first time in the Reply Brief without a showing of good cause, and the Examiner has not been afforded an opportunity to address the argument, we decline to consider its merits.

Exposure Prior to Administration

Appellant next argues that the operation of the cited prior art combination would require "exposure to the needle, exposure to the medicament, or both, prior to administration to a patient," and would therefore destroy sterility of the device prior to use. Appeal Br. 8. According to Appellant, the sterility of Fox's medicament and injection member "would be destroyed when the syringe body assembly 10 is attached onto the needle-holding member 21 **prior** to injection." *Id.* at 9.

The Examiner responds that this argument relies on an embodiment of Fox (Figure 6) with a slit 36, not the embodiment of Fox (Figure 7 – without a slit) used in the Examiner's proposed combination. Ans. 8. According to

the Examiner, Fox's first housing 21' can be "made an integral part of the barrel of the syringe assembly." *Id.* at 9.

The Examiner also responds that the claims recite an article of manufacture, not a method of use, such that the functional language "a container **for** storing a medicament and an injection member in a sterile condition until injection" and "**configured** to seal the second housing to maintain sterility of the injection member" are not structural limitations. *Id.* at 10–11. The Examiner notes that a sterile medicament is "positively required," whereas "sterility of the needle is not of concern of the instant claims, rather only of concern is its capability to provide a housing construction capable of, or configured to," maintain sterility of the injection member. *Id.* at 11. The Examiner contends that, if Fox's injection member is reasonably presumed to be pre-sterilized, the proposed combination of references will prevent contaminants from infiltrating the second housing, and maintain sterility of the injection member and the medicament. *Id.* at 12. The Examiner continues that: (1) Cooper expressly contemplates providing a syringe that is pre-filled, sterilized, and sealed; (2) Wien discusses the sterility of syringe implements; and (3) Jennings discloses "supplying 'packaged sterile' medical equipment." *Id.* The Examiner concludes that even if "sterility of the injection member/needle of the instant claims is positively required," the disclosures of Cooper, Wien, and Jennings teach or suggest "providing pre-filled, prepackaged, invasive medical sharps and hypodermic syringes in order to accomplish the well-known goal of preventing infection associated with a needle stick." *Id.* at 13.

We disagree with the Examiner's statement that "sterility of the needle is not of concern of the instant claims." However, the Examiner

nevertheless correctly considers whether the prior art combination would be capable of providing the claimed function of maintaining needle sterility. Thus, the Examiner has the better argument. The embodiment of Fox's Figure 7 would not expose the needle prior to the needle piercing the barrier 33. Further, the disclosures of Cooper, Wien, and Jennings are directed to maintaining sterility of pre-packaged and pre-filled needles. The prior art thus discloses a container for storing a medicament and an injection member in a sterile condition until injection, and the proposed combination of references is configured to seal the second housing via barrier 33 of Fox and seal 13 of Jennings added thereto, to maintain sterility of the injection member.

Second Containment Barrier

Regarding the Examiner's reliance on Wien and Jennings to disclose a second containment barrier, Appellant contends that the proposed combination "fails to teach or suggest the second contaminant barrier between the shoulder and flange to prevent contaminants from entering the second housing ... to maintain sterility" as claimed. Appeal Br. 9. According to Appellant, Jennings' seal 13 "moves relative to the rigid body 10," such that it is not placed between the rigid body 10 (first housing) and the sleeve 22 (second housing). *Id*. Appellant then contends that, *inter alia*, modifying Fox by placing Jennings' seal 13 between Fox's flange at 63 and shoulder at 42 to ensure a sealed chamber for Fox's needle "would not prevent contaminants from entering the needle assembly, and would not maintain sterility of the injection member." *Id.* at 9–10.

We are not persuaded by Appellant's arguments. Appellant provides no evidence or explanation supporting the contention that Jennings' seal 13

"moves" relative to its rigid body 10, and fails to explain why such movement would prevent the Examiner's proposed combination from "prevent[ing] contaminants from entering the second housing" or "seal[ing] the second housing to maintain sterility" (Appeal Br. 9). Further, for the reason discussed above, we disagree that using Jennings' seal in Fox's device would "interfere with the operation of the Fox device" by impeding the necessary movement thereof.

Preventing Entry of Contaminants

Appellant further argues that "providing an o-ring structure . . . between elements 63 and 42 of Fox would *not prevent contaminants* from entering the needle assembly, and would *not maintain sterility* of the injection member until the injection member traverses the first housing during an injection," because Fox's second housing "includes a guide slot 36 which extends throughout most of the length of the wall of the needle assembly and would allow contaminants to enter the needle assembly prior to or during manipulation of the needle assembly." Appeal Br. 10.

The Examiner responds that the second housing 22' of the embodiment of Fox relied upon in the rejection (i.e., the embodiment of Figure 7) contains no slot and can be made "an integral part of the barrel of the syringe body assembly," so that Appellant's so that attachment of assembly parts need not negatively impact sterility in Fox. Ans. 13. The Examiner also reiterates that Cooper "clearly contemplates pre-filling of syringes" so that, while not required by the actual text of the claims, it would have been obvious "to provide the device of Fox, as modified, pre-filled and prepackaged in a sterile state whereby the needle holder member is

integrally formed as part of the syringe body," with no handling prior to injection to negatively impact device sterility. *Id.* at 13–14.

The Examiner further argues that Wien discloses a similar needle safety shield for "providing a sealed, sterile chamber that isolates and seals a needle in an air tight arrangement," providing motivation to similarly construct Fox's safety shield "in a sealed, air-tight arrangement to . . . maintain[] sterility of the needle prior to use and preventing cross-contamination by the needle after use." *Id.* at 14–15. Likewise, the Examiner finds, Jennings discloses controlling needle exposure and sealing the proximal opening between housings with a wiping ring seal "ensuring that no fluid can leak therepast in either direction." *Id.* at 15. According to the Examiner, providing Fox with a second contaminant barrier between its first and second housings, to ensure that the housings form a sealed chamber for the needle, is described by Wien as beneficial. *Id*. Thus, the Examiner argues, the prior art provides teachings and motivation to modify Fox "to seal the needle from contamination prior to use [and] protect a contaminated needle from leaking fluids to the environment." *Id*.

Because the embodiment of Fox relied on by the Examiner does not include a guide slot 36, and because the prior art provides teachings and motivation to provide a seal between the first and second housings of Fox to maintain sterility, substantial evidence supports the Examiner's determination the prior art combination is capable of preventing contaminants from entering the needle assembly and maintaining sterility of the injection member until injection occurs.

Design Choice

Regarding the Examiner's contention that "the precise location of the second contaminant barrier on the head/flange of the modified device of Fox is a product of obvious design choice" (Final Act. 11), Appellant argues that "[t]he particular location for placement of each contaminant barrier on the device is critical for the functionality of the device in maintaining sterility." Appeal Br. 12, Reply Br. 3. According to Appellant, "placement of the contaminant barrier between the shoulder and the flange in the claimed embodiments allows sliding of the second housing over the first housing by applying pressure to the plunger," and placement at another location, such as between elements 63 and 42 of Fox, would create a substantial resistance to this sliding motion. Reply Br. 3.

Despite Appellant's claim of criticality of location, we are not persuaded that the Examiner erred. A stated above, "[a] person of ordinary skill in the art is also a person of ordinary creativity, not an automaton" and, "in many cases . . . will be able to fit the teachings of multiple patents together like pieces of a puzzle." *KSR*, 550 U.S. at 420–21. We simply are not persuaded that a skilled artisan would be unable to employ a second containment barrier like Jennings' seal 13 between Fox's housings in a manner that seals Fox's needle 28 while allowing operation of Fox's device for injection.

Combining the Five Prior Art References

Appellant next contends that the Examiner failed to articulate a reason why a skilled artisan "would have been motivated to combine the five (5) cited references in such a way as to teach the elements of claim 1," and "[t]he only possible motivation to combine these references to teach or

suggest every element of claim 1 would be a result of improper hindsight reasoning." Appeal Br. 11.

The Examiner responds that the rejection articulates a motivation, found in the prior art itself, for modifying Fox based on the disclosure of each of Hjertman, Cooper, Wien, and Jennings. Ans. 22. More specifically: (1) the teachings of Hjertman are provided to "permit automatic re-extension of the needle shield to automatically protect a user from accidental needle sticks;" (2) the teachings of Cooper are provided "to ensure that the medicament (and the hypodermic injection device itself) is provided in a sterile condition to the user . . . to prevent infection;" (3) the teachings of Wien are provided to "ensure proper procedures are taken to ensure that the interior of the telescoping shield/jacket/housing remains fluid-tight and sealed . . . to . . . protect the needle against contamination prior to needle penetration and prevent cross-contamination by the used needle after penetration;" and (4) the teachings of Jennings are provided to "ensure that the rear of the needle jacket/housing/shield remains fluid tight after use to ensure that contaminated bodily fluids do not leak therepast." *Id*.

We discern no missing reasoning on the Examiner's part, and Appellant has not explained why any of the proffered reasons lack a rational basis. We are not persuaded of Examiner error.

For the reasons explained above, we sustain the rejection of independent claim 1. Claims 2, 4, 5, 7–10, and 22 fall with claim 1.

Rejection II – Claims 11–13, 15, 16, 18–21, and 23

Appellant relies on arguments addressed above regarding claim 1. Appeal Br. 13–14. For the reasons set forth above, we are not persuaded by Appellant's arguments. We sustain Rejection II.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1, 2, 4, 5, 7–10, 22	103	Fox, Hjertman, Cooper, Wien, Jennings	1, 2, 4, 5, 7–10, 22	
11–13, 15, 16, 18–21, 23	103	Fox, Hjertman, Cooper, Wien, Jennings, Erez	11–13, 15, 16, 18–21, 23	
Overall Outcome			1, 2, 4, 5, 7–13, 15, 16, 18–23	

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED