

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte FRANCESCO PELUSO, PATRICK BALTEAU,
ERIC HENAUT, BARBARA MANDARD,
JEAN-PIERRE HARTMAN, VINCENT HOUWAERT,
GIORGIO CANTONI, and SILVANO SFORACCHI

Appeal 2007-1993
Application 10/277,432
Technology Center 3700

Decided: June 14, 2007

Before DONALD E. ADAMS, DEMETRA J. MILLS, and ERIC GRIMES,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a container for administering medical solutions. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

BACKGROUND

“Containers for the administration of medical solutions are well known. Typically, the containers are made from flexible film that is folded and sealed together along peripheral side edges” (Specification 1). The containers also typically have an inlet, outlet, and “a device for piercing the outlet and establishing a fluid communication between the device and the solution inside the container” (*id.*).

The Specification discloses “a formed, filled, sealed solution container with an access port . . . [that] is sealed to the container and has means to puncture said container” (*id.* at 3). The port has a valve with a cylindrical opening slidingly coupled to a perforator that punctures the film, allowing fluid communication between the interior and exterior of the container (*id.* at 3-4). In one embodiment, a “tab is attached to the perforator and attached to the port . . . [so that] the tab is detached from the perforator after the fluid communication is established” (*id.* at 4).

DISCUSSION

1. CLAIMS

Claims 1, 2, 4, 5, 7, and 45-50 are on appeal. Claims 6 and 8-44 are also pending but have been withdrawn from consideration by the Examiner.

Claim 1 is representative and reads as follows:

1. A container comprising:
 - a film folded to define sides wherein the sides are sealed to define an interior;
 - a port defining an outlet through which fluid communication with the interior is established;
 - a perforator movably attached to the port for piercing the film; and

a tab releasably attached to the port wherein detachment of the tab permits the perforator to pierce the film.

Thus, claim 1 is directed to a sealed container made of a film material. The container has a port with a perforator and a tab attached to it. Detachment of the tab allows the perforator to pierce the film.

2. PRIOR ART

The Examiner relies on the following references:

Foran	US 4,767,407	Aug. 30, 1988
Adolf	US 5,334,180	Aug. 2, 1994
Richmond	US 6,068,617	May 30, 2000

3. OBVIOUSNESS -- CLAIMS 1, 2, 4, 5, 7, and 45-49

Claims 1, 2, 4, 5, 7, and 45-49 stand rejected under 35 U.S.C. § 103 as obvious in view of Richmond (Answer 3). The Examiner cites Richmond as disclosing “the device substantially as claimed” (*id.*). The Examiner concedes that Richmond does not disclose that the perforator is movably attached to the port (*id.* at 4).

To meet this deficiency, the Examiner points out that “Richmond clearly discloses a connector and a spike or perforator as a part of his device” (*id.*). The Examiner concludes that one of ordinary skill would have considered it obvious “to attach the spike to the port in the invention disclosed by Richmond, since it has been held that forming in one piece an article that has formerly been formed in two pieces and put together involves only routine skill in the art” (*id.*, citing § MPEP 2144.04).

Appellants argue that Richmond does not “disclose[] or suggest[] a folded-film container having a perforator attached to a port and a tab attached to the port, the detachment of the tab permitting the *perforator* to

pierce the film that forms the container as recited in the present claims” (Br. 11).¹ Regarding the perforating spike disclosed by Richmond, Appellants argue that “the spike 22 is not . . . movably attached to [the] port 24. . . . Moreover, the port 24 to which the conventional spike 22 attaches has no releasably attached tab, the removal of which permits the spike 22 to pierce the container 10” (Reply Br. 4-5).²

We note, as cited in MPEP § 2144.04, that a one-piece structure formed of a plurality of prior art elements has been held unpatentable because using a single construct instead of a multi-element structure was considered “merely a matter of obvious engineering choice.” *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). We also note that the United States Supreme Court recently stated that the analysis under 35 U.S.C. § 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1731, 82 USPQ2d 1385, 1397 (2007).

In emphasizing this flexible approach to obviousness analyses, however, the Supreme Court cautioned that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* at 1740, 82 USPQ2d at

¹ Appeal Brief filed October 12, 2006.

² Reply Brief filed January 12, 2007.

1396 (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

The United States Court of Appeals for the Federal Circuit has also recognized the need for articulated reasoning in support of obviousness rejections, rather than conclusory statements based on precedent-based supposed *per se* rules. *See In re Ochiai*, 71 F.3d 1565, 1571, 37 USPQ2d 1127, 1132 (Fed. Cir. 1995) (“[S]ection 103 requires a fact-intensive comparison of the claimed process with the prior art rather than the mechanical application of one or another *per se* rule.”). Thus, an obviousness evaluation “requires that one compare the claim’s ‘subject matter as a whole’ with the prior art ‘to which said subject matter pertains.’” *Id.* at 1569, 37 USPQ2d at 1131 (quoting 35 U.S.C. § 103).

We do not agree with the Examiner that Richmond suggests the device of claim 1, when the claim is viewed as a whole.

Richmond discloses “a needless valve for use with IV components” (Richmond, col. 1, l. 65). Richmond’s valve has a flexible occluding element that, when deflected, allows fluid communication between the container and the outside (*id.* at Figures 2A and 2B). Figure 2A shows Richmond’s valve in the closed position, with the occluding element 54 blocking fluid communication between the two sides of the valve. As shown in figure 2B, when an urging member 62 is pressed against the flexible element 54, the flexible element 54 is deflected sufficiently to allow fluid communication between the container and the outside.

Richmond’s valve may be deployed in devices having spikes for perforating fluid containers (Richmond, Figure 28). Richmond also

discloses that such spikes “can be advanced into the conventional port 24 until the spike 22 pierces the membrane within the port 24 . . . establish[ing] a path for fluid flow through the port 24” (*id.* at col. 7, ll. 36-38). We agree with the Examiner that this configuration, in which the spike is advanced into the port, constitutes “a perforator movably attached to the port for piercing the film,” as recited in claim 1.

Richmond also discloses (referring to Figure 10) that “each valve 352, 354 can have a respective tamper-resistant cap 356, 358 which is configured to engage a luer fitting,” and that these removable caps can be tamper resistant (*id.* at col. 9, ll. 14-20). We agree with the Examiner that either of these caps can be considered to be “a tab releasably attached to the port wherein detachment of the tab permits the perforator to pierce the film,” as recited in claim 1.

However, claim 1 requires both the movable perforator and the detachable tab to be “attached to the port.” That is, the perforator and detachable tab must be attached to the port at the same time. In contrast, for Richmond’s spike to gain access to the port, the detachable tab must be removed from the port. Thus, to use these features of the device according to Richmond’s teachings, either the perforator would be attached to the port, or the tab would be attached to the port, but the perforator and tab would never be attached to the port at the same time, as required by claim 1.

The Examiner argues that because Richmond’s spike is capable of piercing the container’s film, Richmond meets claim 1’s requirement for a perforator (Answer 5-6). The Examiner argues that Adolf discloses that an access port can be thermally bonded to a fluid bag, and that “[t]herefore, the

port disclosed by Richmond may incorporate not only a secondary membrane, but also the film of the container, depending on how the port is attached to the container” (*id.* at 6). The Examiner concludes that these teachings demonstrate that “the Richmond device has a perforator that is capable of piercing the film of the container, thereby meeting the limitations of the claims” (*id.* at 7).

We are not persuaded by this rationale. The Examiner has not adequately explained how Richmond teaches a device having a detachable tab and a movable perforator, both attached to the access port of a container at the same time, as recited in claim 1. Moreover, the Examiner has not adequately explained how Adolf’s teaching of a thermally bonded access port incorporating the container’s film remedies this shortcoming in Richmond. We therefore do not agree with the Examiner that Richmond would have suggested a device having the features recited in claim 1.

We reverse the obviousness rejection of claims 1, 2, 4, 5, 7, and 45-49 based on Richmond.

4. OBVIOUSNESS -- CLAIM 50

Claim 50 stands rejected under 35 U.S.C. § 103 as obvious in view of Richmond and Foran (Answer 4-5).

Claim 50 depends from claim 49, which depends from claim 1. Claim 50, through claim 49, adds to claim 1 the limitation that the perforator has a tri-slope beveled tip. The Examiner applies Foran to meet this limitation (Answer 5). As discussed above, we do not agree with the Examiner that Richmond teaches or suggests a device that meets the limitations of claim 1. Foran’s disclosure of beveled hypodermic needles does not remedy

Richmond's shortcoming in this regard. We therefore reverse the rejection of claim 50 as being obvious over Richmond and Foran.

OTHER ISSUES

Adolf discloses a "sealed flexible solution container and an attached port assembly that allows for the sterile dispensing of the solution" (Adolf, abstract). Adolf therefore appears to disclose the container and port recited in claim 1.

Adolf also discloses that a "penetrator element is slidably contained within the tubular port and has a contained sharp end for slidably protruding beyond the circumferential flange at the first open end of the tubular port member so as to pierce the film surface and penetrate the sealed chamber" (*id.* at col. 3, l. 65 to col. 4, l. 2; *see also* Figures 5 and 6, item 60). Adolf therefore appears to meet claim 1's limitation of a perforator movably attached to the port.

Adolf also discloses that the port has a "removable cover 80 . . . for closing and maintaining the sterility of the second open end 54 of the tubular port" (*id.* at col. 6, l. 66 to col. 7, l. 2; *see also* Figure 5). As is evident from Figure 5, the removable tab 80 and movable perforator 60 are simultaneously attached to the port, as required by claim 1. Moreover, as shown in Figures 9, 10, and 11, removal of the cover allows insertion of means for urging the perforator into the bag, thereby piercing it (*id.* at Figures 9, 10, and 11). Thus, detachment of Adolf's cover appears to "permit[] the perforator to pierce the film," as recited in claim 1.

Thus, Adolf appears to disclose a device meeting all the limitations in claim 1. Upon return of this case, the Examiner should consider whether

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Adolf anticipates any of the pending claims, or would have made any of the claims obvious when viewed with other relevant prior art.

SUMMARY

We reverse the obviousness rejection of claims 1, 2, 4, 5, 7, and 45-49 based on Richmond, and the obviousness rejection of claim 50 based on Richmond and Foran.

REVERSED

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