

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

Paper No. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RAMESH N. ACHARYA and JOSEPH L. BAKER

Appeal No. 2003-0925
Application No. 09/774,271

ON BRIEF

Before WINTERS, ADAMS and PAWLIKOWSKI, **Administrative Patent Judges**.
PAWLIKOWSKI, **Administrative Patent Judge**.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 48-83.

The examiner relies upon the following references as evidence of unpatentability:

Yukimatsu et al. (Yukimatsu)	4,740,365	Apr. 26, 1988
Stanley et al. (Stanley)	5,288,497	Feb. 22, 1994
Biegajski et al. (Biegajski)	5,700,478	Dec. 23, 1997
Acharya et a. (Acharya)	6,210,699	Apr. 03, 2001
Rouffer	6,221,391	Apr. 24, 2001

"Remington: The Science and Practice of Pharmacy," 19th Edition, Page 1390, Volume II (1995)

On page 4 of the brief, appellants state that the rejected claims are considered to be separately patentable and that the claims do not stand or fall together. On page 2 of the answer, the examiner disagrees with appellants' statement because "applicant only sets forth reasoning as to why the rejected claims are allowable over the cited art and does not appear to set forth reasons in support to why certain rejected claims are separately patentable." We will limit our consideration of the rejected claims before us to only those claims which the appellants have contested with reasonable specificity. See In re Nielson, 816 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987) and In re Wood, 582 F.2d 638, 642, 199 USPQ 137, 140 (CCPA 1978).

Claims 48, 60, and 72 are representative of the subject matter on appeal and are set forth below:

48. A device for transmucosal delivery of active substances comprising at least 50% by weight of a non-plasticized polyvinyl pyrrolidone polymer having a weight average molecular weight of between about 10,000 and 700,000.

60. A device for transmucosal delivery of active substances comprising an adhesive consisting essentially of at least 50% by weight of a non-plasticized polyvinyl pyrrolidone polymer having a weight average molecular of between about 10,000 and 700,000.

72. A device for oral transmucosal delivery of active substances to the oral cavity comprising a mucoadhesive layer and at least one overlying active substance layer said mucoadhesive layer having one surface adapted to contact the mucosal surface of the oral cavity for adhering thereto and an opposing surface in contact with and adhering to an overlying active substance containing layer characterized in that the mucoadhesive layer contains a mucoadhesive composition consisting essentially of at least 50% by weight of a non-plasticized polyvinyl pyrrolidone polymer having a weight average molecular weight of between about 10,000 and 700,000.

Claims 48, 49, 50, 60, 61, and 62 stand rejected under 35 U.S.C. § 103 as being unpatentable over Biegajski, in combination with Remington or Biegajski, and further in view of Rouffer.

Claims 48-53, 55, 57, 60-65, 67, and 69 stand rejected under 35 U.S.C. § 103 as being unpatentable over Biegajski in combination with Remington, and further in combination Stanley or Beijaski, in combination with Rouffer, and further in combination with Stanley.

Claims 48-50, 53-56, 58-62, 65-68, 70, and 71 stand rejected under 35 U.S.C. § 103 as being unpatentable of Biegajski in combination with Remington, and further in combination with Yukimatsu or Biegajski, in combination with Rouffer, and further in combination with Yakimatsu.

Claims 48-50, 60-62, and 72 stand rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-47 of Acharya.

Claims 72-77, 79, and 81 stand rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over the claims of Acharya in view of Stanley.

Claims 72-74, 77-80 and 82-83 stand rejected under judicially created doctrine of obviousness type double patenting as being unpatentable over the claims of Acharya in view of Yukimatus.

We note that the anticipation rejection of claims 48-50 and 60-62 has been withdrawn as indicated on page 3 of the answer.

OPINION

We have carefully reviewed appellants' brief and the examiner's answer and the applied art. Based upon this extensive review, we reverse each of the 35 U.S.C. § 103 rejections.

With regard to the rejections under the judicially created doctrine of obviousness-type double patenting, we affirm these rejections for the following reasons. We observe that appellants do not cite any authority supporting their argument on page 21 in the brief that these rejections are "moot as an appropriate disclaimer will be filed". Nor do appellants controvert the merits of the obviousness-type double patenting rejections. Appellants do not dispute that the instant claims define merely an obvious variation of the invention claimed in U.S. Patent No. 6,210,699. On these facts, we summarily affirm the examiner's obviousness-type double patenting rejections. We note appellants' "intention" to file a terminal disclaimer in this case. Brief, page 21.

Our reasons for reversing each of the 35 U.S.C. § 103 rejections are set forth below.

Beginning on page 14 of the brief, appellants' common argument for all of the 35 U.S.C. § 103 rejections pertains to the claim requirement of a device for transmucosal delivery of active substances comprising a non-plasticized PVP polymer. Each of the independent claims recites this feature.

Beginning on page 14 of the brief, appellants argue that there is a lack of motivation to modify or combine the references. Appellants state that the claims of the present invention specifically recite a transmucosal delivery device that contains at least 50% by weight of a non-plasticized PVP polymer. Appellants state that Biegajski teaches, at column 7, lines 7-11, "[i]n one general aspect, the invention features a water soluble pressure-sensitive adhesive including a water-soluble polymer that is made tacky (that is it is rendered pressure-sensitive) at room temperature by addition of a water-soluble plasticizer that is miscible with a polymer." Appellants state that a number of other statements about the inclusion of a plasticizer in the composition are found throughout Biegajski. Appellants argue that the continual recitation and examples of combining a plasticizer with PVP in order to form a pressure sensitive adhesive layer not only fails to provide any teaching or suggestion that a non-plasticized PVP could be used, but such repetition and consistency also teaches away from such a premise. Brief, pages 14-15.

The examiner also recognizes that Biegajski teaches a plasticized PVP. Answer, pages 7 and 9. The examiner asserts, however, that while appellants claim a non-plasticized PVP, appellant is "merely assigning a different name to the PVP of the instant claims". Answer, page 7. The examiner refers to page 19 and 20 of appellant specification and states that the examples disclose that plasticizers are included in the composition. The examiner relies upon Remington and Rouffer to show that in fact the ingredients disclosed in appellants' specification are plasticizers, and their inclusion results in a PVP composition that is plasticized. The examiner states "[w]hether the PVP itself is non-plasticized is of no bearing since its inclusion with known plasticizers would render it plasticized. Accordingly, it is the position of the examiner that the PVP of the instant claims is indeed plasticized". Answer, pages 7-8.

Each of the independent claims requires a "non-plasticized" PVP polymer. Appellants' specification discloses that it has been discovered that PVP, without the presence of a plasticizer, provides benefits such as reduction in unpleasant flavor and oral irritation, simplification and reduction of the cost of manufacture, and a mucoadhesive that does not interact with ionic active substances. See page 6, line 14 through page 7, line 21. Appellants device can be either a laminated film or tablet, having at least 2 layers, including (1) a basal layer of a pressure-sensitive, water-soluble, non-plasticized PVP mucoadhesive composition, which may or may not contain an active agent, and (2) an active agent containing water soluble polymer layer. See pages 18, line 19 through page 19, line 2.

The adhesive layer is prepared by mixing PVP, copolymers, and tableting excipients and binding compounds such as sorbitol, dyes, flavors, magnesium stearate, mannitol, and the like. See page 19, lines 16-18. It is this disclosure that the examiner asserts results in a plasticized PVP because of the addition of sorbitol or mannitol. At lines 18-19 of page 19, the specification states that the mixture can be formulated as a dry mix or accomplished by conventional wet granulation and screening techniques followed by drying. Example 1, on page 22, indicates that the adhesive layer includes, as an ingredient, mannitol, from 0 to 80%. Example 2 on page 23 indicates that the adhesive layer contains 60% non-plasticized PVP. Example 3 on page 24 indicates that the adhesive layer contains 60% non-plasticized PVP and 10% of an acrylic copolymer. Every other example indicates the use of a non-plasticized PVP. See pages 25-34.

In view of the above disclosure found in appellants' specification, it appears that although ingredients such as sorbitol or mannitol can be included (but not required) in the mixture for making the adhesive layer, the use of a non-plasticized PVP polymer as a mucoadhesive for a transmucosal delivery device is clearly set forth.

We note that the initial burden of presenting a prima facie case of unpatentability on any ground rests with the examiner. See In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Also, during patent examination, the pending claims must be interpreted as broadly as their terms reasonably allow. When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). In determining the patentability of claims, the PTO gives claim language its "broadest reasonable interpretation" consistent with the specification and claims. In re

Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997) (citations omitted).

Here, the examiner interprets appellants' claim as using a plasticized PVP polymer because of certain ingredients set forth in appellants' specification that can be mixed with the PVP polymer. We find that the examiner's interpretation fails in two ways. First, the examiner concludes that the PVP polymer is plasticized based upon certain ingredients that can be mixed with the PVP polymer. Yet, the examiner does not support this conclusion sufficiently. For example, the examples in appellants' specification allow for 0% mannitol. Certainly, this amount would not plasticize the PVP polymer. Furthermore, the examiner does not explain what amount of mannitol would be needed to plasticize the PVP polymer. Secondly, the examiner's interpretation of the claims is not consistent with the specification. As demonstrated above, with regard to appellants' specification, each example states that a non-plasticized PVP polymer is used as the mucoadhesive.

Hence, because the examiner's interpretation of the claims is incorrect, the examiner's application of the references does not support a prima facie case of obviousness of what is really being claimed, i.e., a device for transmucosal delivery of active substances comprising a non-plasticized PVP polymer.

Conclusion

In view of the above, we **reverse** each of the 35 U.S.C. § 103 rejections, but we **affirm** each of the obviousness-type double patenting rejections.

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

AFFIRMED-IN-PART

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Administrative Patent Judge)
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) BOARD OF PATENT
) APPEALS AND
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