

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte REINHARD ALBERS,
RALF DUJARDIN,
HEINZ PUDLEINER,
JOACHIM SIMON,
GUNTHER EBERZ,
WOLFGANG KREISS, and
CHRISTINA KRASEMANN-SHARMA

Appeal No. 2003-0839
Application No. 09/646,339

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, 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 1, 3, 4, and 8. Claim 2 is also pending, but Appellants have not appealed the rejection of claim 2. See the Appeal Brief, page 2.

Claim 1 is representative of the appealed claims and reads as follows:

1. Moulded items made from a thermoplastically processable polyurethane containing a homogeneous distribution of an antibiotic substance which have a peak-to-valley surface roughness of $<5 \mu\text{m}$.

The examiner relies on the following references:

Darouiche et al. (Darouiche)	5,624,704	Apr. 29, 1997
Solomon et al. (Solomon)	5,707,366	Jan. 13, 1998

Claims 1, 3, and 4 stand rejected under 35 U.S.C. § 103 as obvious in view of Solomon.

Claim 8 stands rejected under 35 U.S.C. § 103 as obvious in view of Solomon and Darouiche.

We reverse.

Background

The specification discloses that the use of polymeric materials in medicine “has led to a dramatic increase in so-called foreign body infections / polymer associated infections.” Page 1. For example, “central venous catheters are responsible for about 90% of all cases of sepsis in intensive medicine.” Page 2. Attempts have been made to decrease infections associated with polymeric medical articles by incorporating antimicrobial compounds into them, either at the surface or within the polymer matrix. See pages 2-3.

The specification discloses “moulded items made from thermoplastic polyurethanes which contain a homogeneous distribution of an antibiotic substance and which have a peak-to-valley surface roughness of $<5 \mu\text{m}$.”

Page 4. Such items are disclosed to “effectively prevent surface colonisation by bacteria for a relatively long period (2-4 weeks).” Id.

Discussion

Claim 1, the only independent claim on appeal, is directed to molded items (e.g., medical articles) made from a thermoplastic ally process able polyurethane, containing an antibiotic substance and having a peak-to-valley surface roughness of less than 5 µm. The examiner rejected all the claims as obvious in view of Solomon, either alone or in combination with Darouiche. (The examiner cited Darouiche only for its disclosure of items containing the antibiotic ciprofloxacin; since none of the claims are limited to ciprofloxacin-containing items, we will say no more about Darouiche.)

The examiner cited Solomon for its disclosure of “an anti-infective medical article having chlorhexidine distributed throughout a polyurethane base layer. . . . The bulk distributed chlorhexidine, due to the hydrophobic nature of the polymer, migrates slowly to the surface when the article is in contact with a body fluid and produced anti-infective activity of long duration.” Examiner’s Answer, page 3. The examiner acknowledged that “Solomon does not explicitly teach the medical article . . . having a specific surface roughness.” Id. She concluded, however, that

it would be obvious to one of ordinary skill in this art, at the time of invention . . . , by routine experimentation, to determine a suitable surface roughness to control the rate of release as desired by Applicant[s]. . . . The cited reference teaches the same properties (such as a polyurethane containing a homogeneous distribution of an antibiotic substance) and the same effect (a long duration of release . . .). Therefore, there is no criticality established in the

[peak]-to-valley surface roughness. The expected result would be an [sic] molded item made from polyurethane and an antibiotic in order to provide a device with a controlled release of the active substance over a long duration.

Examiner's Answer, page 4.

Appellants argue, among other things, that Solomon does not “teach or fairly suggest modifying the surface of their articles such that they would have a peak-to-valley roughness of $< 5 \mu\text{m}$.” Appeal Brief, page 4.

“[T]he examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). “The test of obviousness vel non is statutory. It requires that one compare the claim's ‘subject matter as a whole’ with the prior art ‘to which said subject matter pertains.’” In re Ochiai, 71 F.3d 1565, 1569, 37 USPQ2d 1127, 1131 (Fed. Cir. 1995) (quoting 35 U.S.C. § 103).

“The Patent and Trademark Office (PTO) must consider all claim limitations when determining patentability of an invention over the prior art.” In re Lowry, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994). See also In re Angstadt, 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976) (“[W]e must give effect to all claim limitations.” (emphasis in original)).

In this case, we agree with Appellants that Solomon would not have suggested the instantly claimed products. Claim 1 is limited to products having “a peak-to-valley surface roughness of $<5 \mu\text{m}$.” The examiner has acknowledged that Solomon does not teach this limitation. Although the examiner argues that

those skilled in the art could have made products with the recited property “by routine experimentation,” she has pointed to no evidence that those skilled in the art would have been motivated to do so. See In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.”

The examiner argued that those skilled in the art would have been led to modify the surface roughness of the prior art products “to determine a suitable surface roughness to control the rate of release.” Examiner’s Answer, page 4. Thus, she argued, “one would determine a suitable surface roughness in order to obtain the desired effect of controlled release.” Id. “[T]he discovery of an optimum value of a variable in a known process is normally obvious,” but one of the exceptions to that rule is where the parameter optimized was not recognized in the prior art as one which would affect the results. See In re Antonie, 559 F.2d 618,620, 195 USPQ 6, 8 (CCPA 1977). Here, the examiner has cited no evidence to show that those skilled in the art would have recognized a relationship between surface roughness and rate of release.

“Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.” In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000). Modifying “prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a

blueprint for piecing together the prior art to defeat patentability—the essence of hindsight.” In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (citations omitted). The examiner’s rejections in this case are based on improper hindsight and must be reversed.

Summary

We reverse the rejection of claims 1, 3, 4, and 8 because the examiner has not shown that the prior art would have suggested products having a peak-to-valley surface roughness of <5 µm. Those claims are not subject to any outstanding rejections. Claim 2, however, remains rejected under 35 U.S.C. § 103 because Appellants did not appeal the rejection of claim 2.

REVERSED

William F. Smith)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Donald E. Adams)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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