

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. 10

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte NED ALLEN GODSHALL

Appeal No. 2000-1682
Application No. 08/845,503

ON BRIEF

Before CALVERT, STAAB, and CRAWFORD, Administrative Patent Judges.

CRAWFORD, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 through 7 and 10 through 12.

The appellant's invention relates to a method and apparatus for the transdermal delivery of a compound. An understanding of the invention can be derived from a reading of exemplary claims 1 and 4, which appear in the appendix to the appellant's brief.

The prior art

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Ganderton et al. (Ganderton)	3,814,097	June 4, 1974
Gerstel et al. (Gerstel)	3,964,482	June 22, 1976
Gross et al. (Gross)	5,279,544	Jan. 18, 1994
Blinov et al. (SU 1296174)	SU 1296174 ¹	Mar. 15, 1987

The rejections

Claim 12 stands rejected under 35 U.S.C. § 102(b) as being anticipated by SU 1296174.

Claims 1 through 5, 10 and 11 stand rejected under 35 U.S.C. § 102(b) as being as being anticipated² by Gerstel.

Claims 1 through 5, 10 and 11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ganderton.

¹ Our understanding of SU 1296174 is based upon a translation prepared by the U.S. Patent and Trademark Office (PTO). A copy of that translation accompanies this decision.

² A final rejection of claims 8 and 9 under 35 U.S.C. § 103 as being unpatentable over Ganderton, Gross or Gersteland further in view of Glikfeld has been withdrawn. (Answer at page 10).

Claims 1 through 5, 10 and 11 stand rejected under 35 U.S.C.

§ 102(b) as being anticipated by Gross.²

Claims 6-7 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. § 103 as obvious over Ganderton, Gross or alternatively Gerstel.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the answer (Paper No. 8) for the examiner's complete reasoning in support of the rejections, and to the brief (Paper No. 7) for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

We turn first to the examiner's rejection of claim 12 under 35 U.S.C. § 102(b) as being anticipated by SU 1296174. The examiner finds that SU 1296174 discloses a plurality of microprotrusions that are of different length coupled to a housing with a reservoir therein.

The appellant argues that there is no teaching in SU 129617 that the device cuts through a first layer of skin into a second layer of skin when the device is moved parallel to the surface of the skin.

The examiner states that statements of intended use are given weight to the extent that the references must be capable of performing the function. The examiner finds that the sharp distal tip of the microprotrusions of SU 1296174 are inherently capable of providing a cut into the skin of a patient since needles in the medical art have extremely sharp distal tips for penetrating skin and that dragging the tip across a patient's skin would most certainly create a wound.

The SU 129617 device includes needles 9 which are inserted under the skin by pressing the upper end face of body 1 until an electrode 3 comes in contact with the patient's

skin. (Page 3; also see Fig. 1). In our view, the examiner had a reasonable basis for finding that the SU 129617 device is inherently capable of cutting through a first layer of skin when the device is moved parallel to the surface of the skin. As such, we conclude that the examiner has established a prima facie case of anticipation based on inherency.

After the PTO establishes a prima facie case of anticipation based on inherency, the burden shifts to the appellant to prove that the subject matter shown to be in the prior art does not possess the characteristics of the claimed invention. See In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986). Hence, appellant's burden before the PTO is to prove that the microprotrusions disclosed in SU 1296174 are not capable of performing the functions defined in the claims. The appellant has not submitted any evidence to prove that the SU 1296174 microprotrusions are not capable of cutting through the first layer of skin into the second layer of skin when the device is moved parallel to the surface of the skin. We note

that argument of counsel is no substitute for evidence. In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972).

In view of the foregoing, we will sustain the rejection of claim 12 as anticipated by SU 1296174.

We turn next to the examiner's rejection of claims 1 through 5, 10 and 11 under 35 U.S.C. § 102(b) as being anticipated by Gerstel. It is the examiner's opinion that Gerstel discloses:

. . . "microprotrusions" with an elongate crosssections which are described as puncturing projections and "puncturing projections includes any projections adapted to puncture, penetrate, *scrape or cut* the stratum corneum. The projections can be of any geometric shape and diameter that leads itself to be made into projections, such as needles, spikes, tines, pointed triangles, pointed cones, pyramidal points, hollow or solid with an opening at one or at both ends thereof, and the like"(emphasis added). . . The examiner also considers the cutting tips of the needle configurations to be blades as well. Gerstel teaches that the length of the microprotrusions are to vary from .5 um to 100 microns in length (column 7, lines 64-65) which clearly overlaps applicant's disclosed range of 50um to 75um.
[examiner's answer pages 4 and 5]

Appellant argues that Gerstel teaches that the projections do not cut into the underlying epidermis.

Appellant quotes portions of the Gerstel disclosure which appellant argues demonstrate that the Gerstel device does not penetrate the stratum corneum (See brief at page 5).

Most of the language of Gerstel quoted in the brief is directed to the puncturing of the stratum corneum but is silent about the layers of skin underlying the stratum corneum. In regard to the portion of Gerstel quoted in the appellant's brief which indicates that the interior layers of the skin are not punctured, scraped or cut *to a substantial extent* (col. 2, line 14), we note that by using the phrase "to a substantial extent" Gerstel discloses that some non zero puncturing, scraping and cutting of the interior skin may take place when the Gerstel device is utilized.

Gerstel discloses that the height of the projections is subject to variations that correspond to the natural thickness of the skin (col. 7, line 54). Gerstel also discloses that the microprojections are 5 microns to about 100 microns in length which is within the range of lengths (50 microns to 175 microns) for the microprotrusions disclosed in appellant's specification.

Appellant's specification also indicates that the precise length of the microprotrusions needed to disrupt the stratum corneum may vary from patient to patient because of differences in the thickness of the stratum corneum between patients and other surface characteristics of the patient's skin and may also vary from delivery site to delivery site on the same patient (specification at page 7). As there are these differences in the thickness of the stratum corneum from patient to patient and from delivery site to delivery site on the same patient (specification at page 7), it is our view that for at least some patients the microprotrusions of Gerstel would be capable of cutting into the underlying epidermis, which is all that apparatus claim 1 requires.

We note that Gerstel does not seem to disclose blades of elongated cross section. However, appellant does not argue this as a difference and thus it will be assumed that this limitation is met by Gerstel. Cf In re Baxter Travenol Labs, 952 F.2d 388, 391, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991) ("It is not the function of this court to examine the claims in greater detail than argued by an appellant, looking for

nonobvious distinctions over the prior art."); In re Wiseman, 596 F.2d 1019, 1022, 201 USPQ 658, 661 (CCPA 1979)(arguments must first be presented to the Board).

In view of the foregoing, we will sustain the examiner's rejection under 35 U.S.C. § 102(b) of apparatus claim 1 as being anticipated by Gerstel. We will also sustain this rejection as it is directed to apparatus claims 2 and 3 as the appellant has not addressed the separate patentability of these claims. In re Nielson, 815 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987).

In regard to method claims 4 and 5, appellant argues that Gerstel does not disclose the step of "determining the depth of the cut that will extend through the stratum corneum of that animal at said delivery site but not penetrate the dermis of that animal at said delivery site."

The examiner is of the opinion that this limitation in claim 4 is met by Gerstel and states:

. . . a step for determining the depth to which the microprotrusions should cut, which is inherent to the manufacturing process of Gerstel since he desires a certain depth of penetration which requires

the determination of the depth of cutting.
[examiner's answer at page 6].

Appellant's specification discloses that a series of microcutters having blades of different length along with ink markers are used to measure the thickness of the layers of skin at a specific delivery site for each patient (specification at page 8). While Gerstel does disclose that the Gerstel delivery device is designed to penetrate the stratum corneum for the administration of a drug without contacting the nerves for achieving an essentially painless drug administration, Gerstel does not disclose that the device is designed for a particular patient and a particular site on the patient to ensure that the device penetrates the stratum corneum without contacting the body of nerves.

In view of the foregoing, we will not sustain the examiner's rejection of method claim 4 or method claims 5, 10 and 11 dependent therefrom.

We turn next to the examiner's rejection of claims 1 through 5 and 10 through 11 under 35 U.S.C. § 102(b) as being anticipated by Ganderton. In support of this rejection, the examiner states:

Ganderton et al is a device similar to Gerstel in that it has a reservoir and a plurality of microprotrusions 3 extending therefrom to deliver drugs transdermally. Ganderton et al teaches a penetration depth of 20 um to 1000 um which covers appellant's entire disclosed range. [examiner's answer at page 6].

The appellant argues that Ganderton does not disclose a blade having an elongated cross-section.

The examiner considers the spikes disclosed in example 5 in Ganderton to be blades as broadly recited in claim 1.

Example 5 of Ganderton discloses that holes are formed by punching a disc with a sewing needle mounted on a chuck and that burrs (to penetrate the skin) are thereby produced. Ganderton describes these burrs as tiny fibre-like spikes (col. 8, lines 53 to 64).

Appellant's specification does not define the term "blade." However, Webster's II New Riverside University Dictionary, Riverside Publishing Company, pg. 179 (1984) defines a blade as "the flat-edged cutting part of a sharpened tool or weapon." It is not clear from the Ganderton disclosure whether the burrs disclosed in Ganderton are flat-edged or whether the

burrs are of some other configuration. Therefore, we will not sustain this rejection as it is directed to claim 1 or claims 2 and 3 dependent therefrom because an anticipation rejection can not be based on an ambiguous disclosure. In re Turlay, 304 F.2d 893, 899, 134 USPQ 355, 360 (CCPA 1962).

In regard to claim 4, appellant argues that this reference does not include a depth determining step as is recited in claim 4. The examiner considers it inherent in Ganderton to include this step since variations in microprotrusion length is envisioned and notes column 6 lines 23-39 of Ganderton as showing that the device is checked to ensure delivery.

While column 6, lines 23-39 of Ganderton does disclose that the Ganderton device is checked for efficacy at a delivery site (the back) of an animal (a rabbit), Ganderton does not disclose that this is a test to determine the depth of cut necessary to penetrate through the stratum corneum but not penetrate the dermis. After all, the Ganderton device would be effective (and thus pass the Ganderton test) whether it penetrates the stratum corneum and not the dermis or penetrates the stratum corneum and the dermis.

In view of the foregoing, we will not sustain this rejection as it is directed to claim 4 or claims 5, 10 and 11 dependent therefrom.

We turn next to the examiner's rejection of claims 1 through 5, 10 and 11 under 35 U.S.C. § 102(b) as being anticipated by Gross. In support of this rejection, the examiner states:

In reviewing appellant's specification and claims, it has been determined that a "blade" may include a microprotusion with a passage extending therethrough. It is unclear where the cutting edge is from appellant's disclosure but one of ordinary skill would conclude that it is on the tip of the microprotrusion (207) as seen in figure 1. The examiner contends that this constitutes nothing more than a needle type configuration. Gross et al teaches such configurations as can be seen in figures 7a-7e . . . [examiner's answer, page 7](emphasis added).

Appellant's disclosure teaches that the simplest embodiment of the present invention comprises a bed of microneedles or microcutters (specification at page 5), but that in the preferred embodiment the microprotrusions are blades (specification at page 7). As such, the appellant's disclosure teaches that a blade is a type of microprotrusion but not that all microprotrusions are blades.

The microprotrusions disclosed in Gross are tubular elements or needles. These tubular elements or needles are not flat edged cutting parts and as such in our view are not blades with elongated cross sections as recited in claim 1. As such, we will not sustain this rejection as it is directed to claim 1 or claims 2 and 3 dependent thereon.

In regard to the recitation in claim 4 of a depth determining step, the examiner argues that the depth determining step is inherent in the Gross disclosure since the skin layer thickness must be determined prior to implementing the Gross device and because the Gross device envisions variations in the length of the microprotrusions.

Gross does not disclose that the microprotrusions cut into the stratum corneum but not into the dermis. Rather, the device pierces the layer of dead cells on the skin. Therefore, the Gross device may very well pierce the layer of dead cells on the skin and extend into and cut the dermis of the skin. As such, we will not sustain this rejection as it is directed to claim 4 or claims 5, 10 and 11 dependent therefrom.

We turn next to the examiner's rejection of claims 6-7
under

35 U.S.C. § 102(b) as anticipated by or in the alternative
under

35 U.S.C. § 103 as obvious over Ganderton, Gross or
alternatively Gerstel et al.

Claim 6 recites the step of "determining if said
microcut extends into the epidermis of that individual at said
delivery site."

As we discussed above, it is our view that Gerstel,
Ganderton and Gross do not disclose this step of determining
the depth of a cut that will extend through the stratum
corneum of that animal at said delivery site but not penetrate
the dermis of the animal at said delivery site. Therefore, in
our view, the cited references do not teach the step of
determining if the cut will extend through the stratum corneum
into the epidermis but not penetrate the dermis for the
reasons stated above in our discussions of the rejections of
claims 4, 5 and 10 and 11. As such, we will not sustain the
rejection of claims 6 and 7 under 35 U.S.C. § 102(b) as being
anticipated by in view Gerstel, Ganderton or Gross.

The examiner argues that if the determining step of claims 6 and 7 is not inherent in the disclosures of Gerstel, Ganderton and Gross, it would have been obvious to do so since testing is required before taking a medical device to the market place.

Neither Gerstel, Ganderton nor Gross discloses or suggests that the skin of a specific animal at a specific delivery site be tested to determine the length of the microprotusions which will penetrate the stratum corneum and not the dermis. Indeed, these references do not teach that the stratum corneum at different sites on an animal would have different thicknesses.

In view of the foregoing, we will not sustain the examiner's rejection of claims 6 and 7 under 35 U.S.C. § 103 as being unpatentable in view of Gerstel, Gross or Ganderton.

In summary:

The examiner's rejection of claim 12 under 35 U.S.C. § 102(b) as being anticipated by SU 1296174 is affirmed.

The examiner's rejection of claims 1 through 3 under 35 U.S.C. § 102(b) as being anticipated by Gerstel is affirmed.

The examiner's rejection of claims 4, 5, 10 and 11 under 35 U.S.C. § 102(b) as being anticipated by Gerstel is reversed.

The examiner's rejection of claims 1 through 5, 10 and 11 under 35 U.S.C. § 102(b) as being anticipated by Ganderton is reversed.

The examiner's rejection of claims 1 through 5, 10 and 11 under 35 U.S.C. § 102(b) as being anticipated by Gross is reversed.

The examiner's rejection of claims 6 and 7 under 35 U.S.C. § 102(b) and anticipated by or in the alternative as obvious in view of Gerstel is reversed.

The examiner's rejection of claims 6 and 7 under 35 U.S.C. § 102(b) and anticipated by or in the alternative as obvious in view of Ganderton is reversed.

The examiner's rejection of claims 6 and 7 under 35 U.S.C. § 102(b) and anticipated by or in the alternative as obvious in view of Gross is reversed.

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

IAN A. CALVERT)	
Administrative Patent Judge)	
)	
)	
)	
)	BOARD OF PATENT
LAWRENCE J. STAAB)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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MURRIEL E. CRAWFORD)	
Administrative Patent Judge)	

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**ATTN: A copy of the Blinov
translation is in the envelope
ready to be mailed.**

APJ CRAWFORD

APJ STAAB

APJ CALVERT

DECISION: AFFIRMED-IN-PART

DRAFT TYPED: 25 Oct 02

FINAL TYPED:

Panel Change: Yes No

3 MEM. CONF. Y N

OB/HD

GAU: 3700

PALM

ACTS 2

BOOK

DISK (FOIA)

REPORT