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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/090,422	04/16/2008	Daniel C. Duan	60693US005	2945
32692	7590	03/08/2013	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			LEE, BRANDY SCOTT	
			ART UNIT	PAPER NUMBER
			3767	
			NOTIFICATION DATE	DELIVERY MODE
			03/08/2013	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* DANIEL C. DUAN

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Appeal 2012-001650  
Application 12/090,422  
Technology Center 3700

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Before DONALD E. ADAMS, ERIC GRIMES, and ULRIKE W. JENKS,  
*Administrative Patent Judges.*

ADAMS, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 22-28 and 34-36 (App. Br. 2; Ans. 3). We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a drug delivery device (claims 22-28) and a microneedle array (claims 34-36). Claims 22 and 34 are representative and are reproduced in the Claims Appendix of Appellants' Brief.

Claims 22-25, 27, 28, and 34-36 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Ameri.<sup>1</sup>

Claim 26 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Ameri and Tanaami.<sup>2</sup>

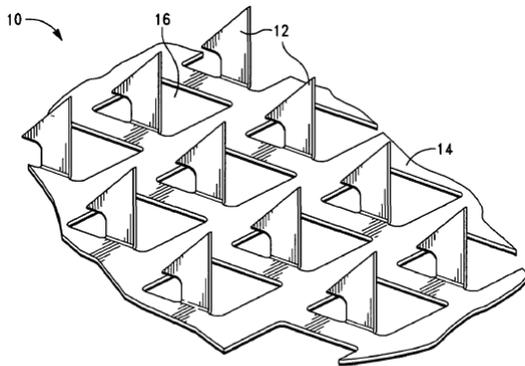
We affirm the rejection of claims 34-36 under 35 U.S.C. § 102(a) as being anticipated by Ameri and reverse all other grounds of rejection.

#### ISSUE

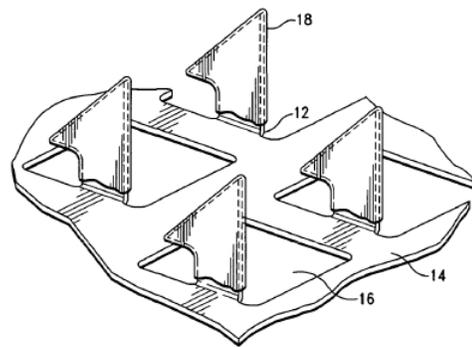
Does the preponderance of evidence on this record support Examiner's finding that Ameri teaches Appellant's claimed invention?

#### FACTUAL FINDINGS (FF)

FF 1. Ameri's figures 11 and 12 are reproduced below:



**FIG. - 11**



**FIG. - 12**

“**FIG. 11** is a perspective view of a microprojection array that would be used in conjunction with the present invention” (Ameri 5: ¶ [0057]; *see* Ans. 5).

“**FIG. 12** is a perspective view of a microprojection array showing several microprojections that have been coated” (*id.* at ¶ [0058]; *see* Ans. 5).

<sup>1</sup> Ameri et al., US 2004/0265354 A1, published December 30, 2004.

<sup>2</sup> Tanaami et al., US 2004/0254559 A1, published December 16, 2004.

FF 2. Ameri teaches “[i]n one embodiment, the microprojection is constructed out of stainless steel, titanium, nickel titanium alloys, or similar biocompatible materials” (*id.* at ¶ [0043]).

FF 3. Ameri teaches coating the first 100 µm of the tips of microprojections with formulations containing hPTH(1-34) and evaluating the amount of peptide coated on the arrays by ultraviolet spectroscopy (*id.* at 8: ¶ [0192]; *see* Ans. 5).

FF 4. Examiner finds that

In ultraviolet spectroscopy, the absorption or reflectance in the visible range directly affects the perceived color of the **chemicals** involved. Since the active agent (18) is a chemical coating the tips (12) of the microneedles only, not the base/substrate (14) as clearly depicted in Figure 12, then it follows that the tip (coated with active agent) of the microneedle would fluoresce a different color than the titanium base of the microneedle when exposed to UV light; therefore providing the coated microneedle and the base with different optical responses ... [and] the coated microneedle a greater fluorescent value than the substrate.

(Ans. 7-8.)

#### ANALYSIS

The delivery device of Appellant’s claim 22 comprises a plurality of microneedles arranged on a substrate and requires, *inter alia*, that (1) the tip of one or more of the microneedles has a first optical response when probed with a selected incident light spectrum; (2) the base of the microneedle has a second optical response differing from the first optical response; and (3) an active agent formulation covers at least a portion of the tip of one or more of the microneedles and *modulates* the first optical response of the

microneedles when probed with the selected incident light spectrum (Claim 22). Claims 23-25, 27, and 28 depend directly from claim 22.

Appellant contends that since Ameri “teaches that the microneedles are made of a single material, [e.g.,] titanium ... the microneedles of Ameri do not have tips having a first optical response and a base having a second different optical response” (App. Br. 4; *see* FF 2). We agree.

Notwithstanding Examiner’s assertion to the contrary, Appellant’s claim 22 requires that one or more of the microneedles on the array exhibit two different optical responses, wherein the first optical response is *modulated* by a coating that is applied to the tip of the one or more microneedles (Appellant’s claim 22; *Cf.* FF 1-5).

Examiner appears to discount the foregoing requirement of Appellant’s claimed invention, wherein the one or more microneedles exhibit two different optical responses *prior to* applying a coating to the tip of the one or more microneedles that *modifies* the first of the optical responses (FF 5; *Cf.* Appellant’s claim 22).

*Claim 34:*

The microneedle array of Appellant’s claim 34 *comprises* a plurality of tapered microneedles arranged on a substrate, wherein the microneedles have a fluorescence that is greater than that of the substrate (Claim 34).

Unlike Appellant’s claim 22, claim 34 does not require that the microneedles have a first optical response that is modulated by a coating. In addition, the claim is open to include a coating on the tips of the microneedles. Therefore, notwithstanding Appellant’s contentions to the contrary, and absent evidence to the contrary, we agree with Examiner’s

finding that Ameri's coated microneedle will inherently exhibit a greater fluorescent value than the uncoated substrate (FF 5; *Cf.* App. Br. 4).

#### CONCLUSION OF LAW

The preponderance of evidence on this record supports Examiner's finding that Ameri teaches the invention of Appellant's claim 34. The rejection of claim 34 under 35 U.S.C. § 102(a) as being anticipated by Ameri is affirmed. Claims 35 and 36 are not separately argued and fall with claim 34.

The preponderance of evidence on this record fails to support Examiner's finding that Ameri teaches the invention of Appellant's claims 22-25, 27, and 28. The rejection of claims 22-25, 27, and 28 under 35 U.S.C. § 102(a) as being anticipated by Ameri is reversed.

*Obviousness:*

#### ISSUE

Does the preponderance of evidence on this record support a conclusion of obviousness?

#### FACTUAL FINDINGS (FF)

FF 5. Examiner relies on Ameri as discussed above (Ans. 6).

FF 6. Examiner finds that Ameri fails to suggest that the incident light spectrum comprises visible wavelengths and relies on Tanaami to suggest the use of "visible light and ultraviolet light in the detection of molecules based on spectroscopy" (*id.* at 6-7).

#### ANALYSIS

Based on the combination of Ameri and Tanaami, Examiner concludes that, at the time Appellant's invention was made, it would have

been prima facie obvious to “modify the device of Ameri with the ability [to] also use visible wavelengths to optimize usage when detecting molecules with shorter wavelengths” (Ans. 7).

Appellant contends that Tanaami “does not overcome the deficiencies of the teachings of Ameri” (App. Br. 4). We agree. Examiner failed to establish that Tanaami makes up for Ameri’s failure to suggest one or more microneedles that exhibit two different optical responses *prior to* applying a coating to the tip of the one or more microneedles that *modifies* the first of the optical responses.

#### CONCLUSION OF LAW

The preponderance of evidence on this record fails to support a conclusion of obviousness. The rejection of claim 26 under 35 U.S.C. § 103(a) as unpatentable over the combination of Ameri and Tanaami is reversed.

#### 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).

#### AFFIRMED-IN-PART

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