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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SUN ILL KIM, SEON JEONG KIM,
and JANG HYUN YOUN[1]

Appeal 2015-003144
Application 13/143,960
Technology Center 3700

Before DONALD E. ADAMS, JEFFREY N. FREDMAN,
and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

PER CURIAM

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a biosensor for analyzing concentration of an analyte which have been rejected as obvious.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] Appellants identify the Real Party in Interest as INDUSTRY-UNIVERSITY COOPERATION FOUNDATION HANYANG UNIVERSITY. (Br. 3.)

[2] The obviousness-type double patenting rejection (*see* Final Act. 5–7) is moot in view of abandonment of US 13/144,324 (*see* Notice of Abandonment issued Nov. 5, 2014).

STATEMENT OF THE CASE

Appellants' invention "relates to a biosensor to which an electroactive polymer layer is attached, and more specifically, to a biosensor including an electroactive polymer layer attached to the surface of a bioreceptor and electrodes connected to the electroactive polymer layer." (Spec. 1:7–10.) The biosensor "allows reversible deformation of the electroactive polymer layer when an electrical stimulation is applied to the electrode and can thereby analyze the concentration of an analyte when the surface of the bioreceptor is exposed to the analyte." (*Id.* at 1:10–13.)

Claims 1 and 3–6 are on appeal. Claim 1 is illustrative:

> 1. A biosensor for analyzing concentration of an analyte, comprising:
>
> a bioreceptor capable of detecting an analyte to be analyzed;
>
> a signal transducer converting concentration information of the analyte detected by the bioreceptor into an analyzable signal;
>
> *at least two electroactive polymer layers attached on a surface of the bioreceptor to close the bioreceptor, the at least two electroactive polymer layers contracting in response to an electrical stimulation to thereby expose the surface of the bioreceptor to the analyte and allowing the bioreceptor to detect the analyte, and restoring to close the bioreceptor when the electrical stimulation is removed after detecting the analyte*; and
>
> an electrode connected to the at least two electroactive polymer layers to apply the electrical stimulation to the electroactive polymer layers.

(Br. 15 (Claims App'x) (emphasis added).)

Claims 1 and 3–6 are rejected under 35 U.S.C. § 103(a) over Shah[3] and Low.[4]

Appellants argue the patentability of the claims together. We select claim 1 as representative.

The Examiner finds that

> Shah teaches a biosensor for analyzing concentration of an analyte (abstract), comprising: a bioreceptor capable of detecting an analyte to be analyzed; a signal transducer converting concentration information of the analyte detected by the bioreceptor into an analyzable signal (par.[]0025). Shah also teaches [that] the invention provides [a] sensor array of analyte sensing elements, optionally within reservoirs/wells and sealed with controllable membranes and which is useful for long term analyte sensing . . . the analyte sensing element can be coated with an expanding hydrogel within the well, such that the voltage-induced dissolution of a portion of the gold membrane induces expansion of the hydrogel, thus mechanically assisting the removal of the membrane from the well's surface (par.[]0032).

(Final Act. 3.) The Examiner finds that

> Shah does not teach at least two electroactive polymer layers contracting in response to an electrical stimulation to thereby expose the surface of the bioreceptor to the analyte and allowing the bioreceptor to detect the analyte, and restoring to close the bioreceptor when the electrical stimulation is removed after detecting the analyte; and an electrode connected to the at least two electroactive polymer layers to apply the electrical stimulation to the electroactive polymer layers.

(*Id.* at 3–4.)

The Examiner, however, turns to Low and finds it teaches

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[3] Shah et al., US 2006/0004272 A1, published Jan. 5, 2006.
[4] Low et al., *Microactuators toward microvalves for responsive controlled drug delivery*, B 67 SENSORS AND ACTUATORS 149–160 (2000).

> a blend of conducting polymer and a hydrogel that contracts and relaxes. In the development of a reversible polymeric valve or artificial muscle, a blend of a conducting polymer and a hydrogel was synthesized and its peculiar property of swelling and shrinking was employed to demonstrate the opening and closing of the passages in a drug reservoir. The conducting polymer in the blend forms the "electronic backbone" of the artificial muscle and is sensitive to pH, applied electrical potential, and chemical potential in its microenvironment. The hydrogel forms the "ionic body" of the muscle and exhibits dramatic effects of swelling and shrinking upon changes in pH, solvent, temperature, electric field, or ambient light conditions. (see Low page 154 section 3.2 "Polymeric valves: artificial muscle (reversible valves)"; Fig.4).

(*Id.* at 4.) The Examiner concludes that it would have been obvious to "modify Shah's degrading reservoirs/wells with Law's reversible valves because doing so would allow for more focused sensor readings, while isolating spent sensor elements from obscuring the newly exposed sensor signal (Shah par.[]0032)," and that "one of ordinary skill in the art at the time of invention would have had predictable success incorporating controllable membranes that open/close in analyte sensing since doing [so] would allow for long term analyte sensing." (*Id.*)

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Shah and Low would have rendered claim 1 obvious?

Findings of Fact (FF)

1. Shah teaches

> A long term analyte sensor for measuring at least one analyte in the body of a user and which includes a housing, a plurality of analyte contacting sensor elements and at least one structure for relaying information away from the sensor. This plurality of analyte contacting sensor elements are typically disposed in an array. The analyte sensor further includes at least one sensor

> protection membrane that is controllable in a manner such that sensor elements may be activated (e.g. exposed to the external environment) at different times so as to extend the useful life of the sensor. In illustrative analyte sensors, the analyte is glucose.

(Shah Abstract; *see also* Final Act. 3.)

2. Shah teaches that "[t]he analyte sensing protection membranes can take a variety of structural forms (e.g. a film, a layer, a cap etc.) as long as they function to reversibly protect the analyte sensing element of the analyte sensing device from the environment into which the analyte sensing device is placed." (Shah ¶ 28; *see also* Ans. 3.)

3. Shah teaches that

> [t]he glucose oxidase can be covered by a material such as a Glucose Limiting Membrane (GLM) within the well or on top of the membrane. In a specific example, the well can be hermetically sealed with a gold membrane until programmed voltage-induced dissolution of the membrane. Alternatively, the analyte sensing element can be coated with an expanding hydrogel within the well, such that the voltage-induced dissolution of a portion of the gold membrane induces expansion of the hydrogel, thus mechanically assisting the removal of the membrane from the well's surface.

(Shah ¶ 32; *see also* Final Act. 3.)

4. Shah teaches that "the analyte sensor membrane can be a material that is permeabilizable in response to an applied signal such as an electric field or current, magnetic field, change in pH, or by thermal, chemical, electrochemical, or mechanical signal." (Shah ¶ 34; *see also* Ans. 3.)

5. Shah teaches

> barrier membranes that reversibly cover both analyte sensing elements as well [as] reservoirs containing compounds that can be controllably released into the environment, include those

> where the compounds in the reservoirs are designed to enhance the function of the analyte sensing device by, for example, reshaping and/or adapting the in vivo tissue environment into which the sensing device is placed.

(Shah ¶ 87; *see also* Ans. 4.)

6. Shah's Figure 2 is reproduced below:

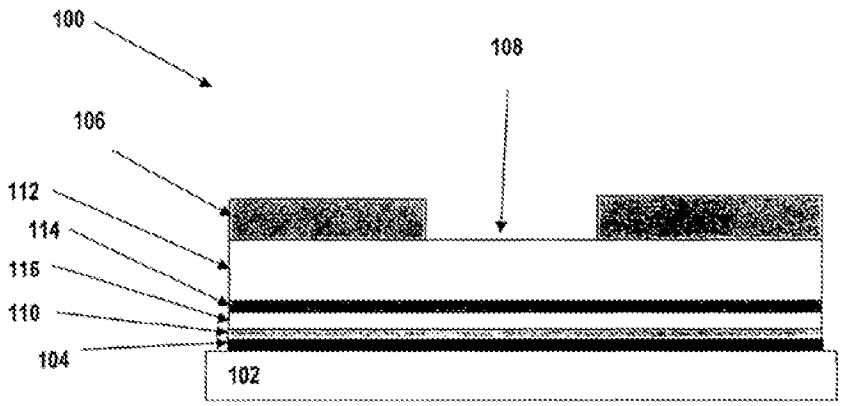

FIG. 2

Figure 2 shows a "sensor **100**" having: (a) a "base layer **102**," (b) a "conductive layer **104** [that] comprises one or more electrodes," (c) "an analyte sensing layer **110**," (d) a "protein layer **116**," (e) "an adhesion promoter layer **114**," (f) an "analyte modulating layer **112**," (g) "an electrically insulating cover layer **106**," and (h) "one or more exposed regions or apertures **108**." (Shah ¶¶ 47–50, 53; *see also* Ans. 4.)

7. Low teaches

> In the development of a reversible polymeric valve or artificial muscle, a blend of a conducting polymer and a hydrogel was synthesized and its peculiar property of swelling and shrinking was employed to demonstrate the opening and closing of the passages in a drug reservoir. The conducting polymer in the blend forms the "electronic backbone"' of the artificial muscle

> and is sensitive to pH, applied electrical potential, and chemical potential in its microenvironment. The hydrogel forms the "ionic body" of the muscle and exhibits dramatic effects of swelling and shrinking upon changes in pH, solvent, temperature, electric field, or ambient light conditions.

(Low 154, second col.; *see also* Final Act. 4.)

8. Low's Figure 4c is reproduced below:

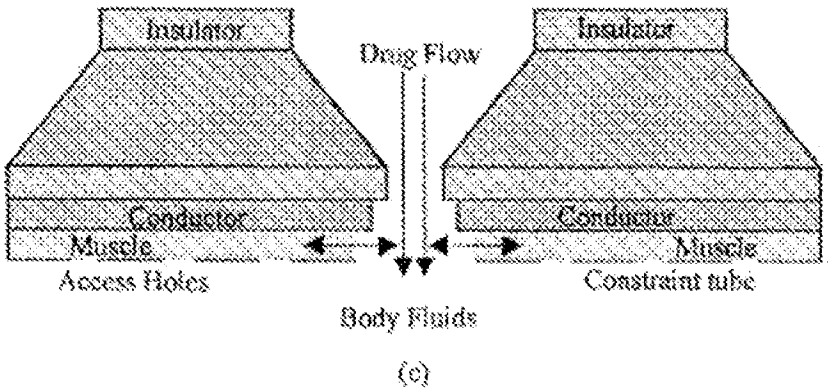

Figure 4c shows "[s]chematic of alternative designs for opening and closing holes in a drug reservoir using the artificial muscle concept." (Low 154, first col., Fig. 4c; *see also* Final Act. 4.)

DISCUSSION

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 3–5; Ans. 2–4; FF 1–8) and agree that claim 1 would have been obvious over Shah and Low. We address below Appellants' arguments.

Appellants contend that "their intended purposes and functions in the claimed invention and Low are different from each other, and thus there is <u>no</u> reason, motivation and expectation for a person, having ordinary skill and not knowing the claimed invention, to combine Low into other prior art to reach the claimed invention." (Br. 10.) Appellants argue that "there is <u>no</u>

need and reason for Shah to combine any additional opening/closing element thereinto." (*Id.* at 13.)

These arguments are unpersuasive.

Shah teaches that "[t]he analyte sensor further includes at least one sensor protection membrane that is controllable in a manner such that sensor elements may be activated (e.g. exposed to the external environment) at different times so as to extend the useful life of the sensor." (FF 1; *see also* FF 2–4, 6.) Shah teaches "barrier membranes that *reversibly* cover both analyte sensing elements as well [as] reservoirs containing compounds that can be controllably released into the environment" (FF 5 (emphasis added); *see also* FF 2.) Low teaches "[i]n the development of a *reversible* polymeric valve or artificial muscle, a blend of a conducting polymer and a hydrogel was synthesized and its peculiar property of swelling and shrinking was employed to demonstrate the opening and closing of the passages in a drug reservoir." (FF 7 (emphasis added); *see also* FF 8.)

As the Examiner explains, "one of ordinary skill in the art would have had predictable success modifying Shah so as to replace [its] protective membrane 106 with Low's two electroactive polymer layers since this would be a simple substitution." (Ans. 4.) "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l v. Teleflex Inc.,* 550 U.S. 398, 416 (2007). "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* at 417. Moreover, an "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout,* 675 F.2d 297, 301 (CCPA 1982).

We thus agree with Examiner that "since both [Shah and Low] are directed towards implantable devices with membranes that function to open/close a reservoir, one of ordinary skill would have had [] reason to combine the two teachings." (Ans. 2.)

Referring to the Examiner's conclusion concerning combining the teachings of Low and Shah, Appellants contend that

> "placing Low's artificial muscle/reversible valves in Shah's one or more exposed regions or aperture 108" **cannot** reach the claimed structures. As clearly recited in Claim 1, the claimed electroactive polymer layers are **attached on a surface** of the bioreceptor, and configured to **expose the surface** of the bioreceptor, **not** simply "placing one or more exposed regions or aperture 108" as in the Examiner's proposed combination.

(Br. 12.)

This argument is also unpersuasive.

As the Examiner explains,

> nothing in claim 1 requires the two electroactive polymer layers to be ***directly*** attached to the bioreceptor. That is to say, the fact that Shah teaches intermediate layers (116, 114, and 112 in Fig.[]2) between sensing layer 110 (i.e. the bioreceptor) and protective membrane 106 (i.e. modified with Low) is not relevant as it is understood that the protective membrane is attached to the surface of sensing layer 110 via the intermediate layers.

(Ans. 4.) During prosecution, we give claim terms the broadest reasonable interpretation as understood by a person of ordinary skill in the art in light of the specification. *In re Morris*, 127 F.3d at 1054 (Fed. Cir. 1997); *In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.1359, 1364 (Fed. Cir. 2004) ("Construing claims broadly during prosecution is not unfair to the applicant . . . because the applicant has the opportunity to amend the claims to obtain more precise claim coverage.")

Appellants contend that

> The Examiner's proposed combination of Low and Shah can lead to mal-operation of Shah and degradation of the Shah's sensing element, due to unnecessary closing/opening of their other structures from the environment. For example, when the Shah's sensing element 110 and other functional structures are closed, the analyte permeated in the analyte modulating layer 112 <u>remains in contact</u> with the sensing layer 110 <u>at a closed state</u>. Then, this situation can result in mal-sensing of the sensing layer 110 for the next sensing operation where the Low's artificial muscle/reversible valves is opened again, and further lead to degradation in the sensibility of the sensing layer 110.

(Br. 13.)

We are not persuaded by Appellants' contention that modifying Shah's device in the manner suggested by the Examiner would have prevented Shah's device from functioning as intended, including some degradation sensitivity of the sensing layer. (*Id.*) Even if sensitivity was reduced somewhat to gain the benefit of providing opening and closing of passages as in Low (FF 7), that would not mean claim 1 is nonobvious. *See In re Urbanski,* 809 F.3d 1237, 1243 (Fed. Cir. 2016) (holding that a combination of references may be obvious even if the combination is at the expense of a benefit of one of the references). Appellants also provide no persuasive factual evidence to show that Shah's device, as modified by the Examiner, would "lead to mal-operation" as Appellants contend. *See In re Geisler,* 116 F.3d 1465, 1470 (Fed. Cir. 1997) ("[A]ttorney argument [is] not the kind of factual evidence that is required to rebut a prima facie case of obviousness").

Appellants argue that "the Examiner's proposed combination cannot reach the claimed invention in the same way that the new claimed invention does, <u>without</u> significant re-design or change in the prior art structures, and

without losing their original intended purposes and associated operation principles." (Br. 13.)

We are also not persuaded that the skilled artisan, desiring the benefit of Low's two artificial muscles (i.e., to open and close passages) in a known analyte sensor, such as that of Shah, would have been unable to design a modified device that maintained a sufficient sensitivity. "[A] person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421. The obviousness analysis "take[s] account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id.* at 417. Appellants have provided no persuasive argument or evidence showing that Examiner's proposed combination of known prior art elements according to their known functions would involve more than routine engineering efforts or that the device, as modified by the Examiner, would not work.

For the above reasons, the preponderance of the evidence supports the Examiner's conclusion that claim 1 would have been obvious.

CONCLUSION OF LAW

We affirm the rejection of claims 1 and 3–6 under 35 U.S.C. § 103(a) over Shah and Low.

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