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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BORU ZHU and HERBERT HENLEY JR.

Appeal 2021-001375
Application 15/800,866
Technology Center 1700

Before MICHELLE N. ANKENBRAND, BRIAN D. RANGE, and LILAN REN, *Administrative Patent Judges*.

REN, ADMINISTRATIVE PATENT JUDGE.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 31–50. *See* Final Act. 15, 23. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as "Ascensia Diabetes Care Holdings AG." Appeal Br. 2.

CLAIMED SUBJECT MATTER

Claim 31, reproduced below, is illustrative of the claimed subject matter:

> 1. An electrochemical test sensor comprising a base, a lid, a plurality of electrodes and a dried reagent, the dried reagent comprise an enzyme, a mediator, a cellulose polymer and a multivalent salt such that dried reagent has a uniformity in which the ratio of the thinnest point to the thickest point is greater than about 0.2, the enzyme including glucose dehydrogenase, the mediator including a 3-phenylimino-3H-phenothiazine or a 3-phenylimino-3H-phenoxazine.

Claims Appendix (Appeal Br. A-1).

REFERENCES

The Examiner's rejections rely on the following prior art references:

Name	Reference	Date
Bateson	US 5,627,075	May 6, 1997
Vreeke	US 7,163,616 B2	Jan. 16, 2007
Karinka	US 2003/0146110 Al	Aug. 7, 2003

REJECTIONS

The Examiner maintains the following rejections:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/Basis
31–37, 39–47, 49, 50	103	Bateson, Vreeke
38, 48	103	Bateson, Vreeke, Karinka

OPINION

The dispositive issue on appeal is whether the evidence before us supports the Examiner's finding that Bateson teaches or suggests an electrochemical test sensor having a dried reagent that "has a uniformity in which the ratio of the thinnest point to the thickest point is greater than about

0.2" as claim 31 requires. The Examiner acknowledges that "Bateson doesn't explicitly disclose" this feature but provides a series of calculations, as well as illustrations to show the prior art teaching. Ans. 12–17, 15.

The Examiner finds that Bateson teaches a wet reagent, which "is placed in well **9**" of a biosensor "so that it covers substantially all of exposed surfaces **10** of electrodes **4** and **5** and preferably covers the exposed surface of layer **2** between the electrodes." Bateson 3:49–51 (cited in Final Act. 16). The Examiner finds that Bateson teaches drying the reagent, which "removes at least about 90% of the water content of the reagent, thereby resulting in a dried reagent." *Id.* at 3:60–63 (cited in Final Act. 16). The Examiner also finds that Bateson teaches well 9 is disposed within layer 3 of the biosensor and layer 3 is 250 microns thick. *Id.* at 3:4–5 (cited in Final Act. 16).

Based on the dimensions of the biosensor in Bateson, the Examiner finds that "[t]he topography of the bottom of the well shows . . . the portion of the reagent extending from above the electrodes to the surface of a reagent are thinner than the portion of the reagent extending from layer 2 to the surface of the reagent." Ans. 15. Using Bateson's teaching of placing 6 microliters of reagent 11 in well 9 (Bateson 3:54–55), as well as the dimensions of the well, the Examiner calculates that removing 90% of the water from reagent 11 would decrease the thickness of the reagent by 72% across the surface of reagent 11 resulting in a ratio of 0.64 between the thinnest and thickest point. *Id.* at 16–17.

Appellant, on the other hand, submits declaratory evidence stating that "[t]he exact percentage of the reduction in thickness would depend on the drying conditions and the crystalline or molecular structure of the dissolved

solid materials in the wet reagent." Declaration by Mr. Daniel V. Brown submitted on October 2, 2019 ("Declaration" or "Decl."), ¶ 21. Mr. Brown states that "details like the contour of the dried reagent" are necessary to calculate the recited ratio because the surface of the dried reagent is not smooth. *Id.* ¶ 27. Mr. Brown cites Figure 9 of the Specification to show that the contoured surface of a dried reagent is not smooth. *Id.* ¶ 27. Mr. Brown also states that the dried reagent in Bateson would exhibit the "coffee ring" effect upon drying. *Id.* ¶ 25. The Specification provides the following explanation of the "coffee ring" effect:

> When a spilled drop of coffee dries on a solid surface, it leaves a dense, ring-like stain along the perimeter. The coffee, initially dispersed over the entire drop, becomes concentrated into a tiny fraction of it. This phenomenon is referred to as "coffee ring" effect. Physically, the coffee ring is formed because any liquid that evaporates from the edge must be replenished by liquid from the interior. As this process ends, more materials are accumulated onto the edge. When an electrochemical test sensor is formed, a chemical reagent including an enzyme and mediator is applied to and dried on an electrode surface. The chemical reagent may be applied by methods such as screen printing, strip coating and micro-deposition. During micro-deposition, the reagent is relatively thin and has a viscosity less than about 1,000 centipoise (cp) and desirably is less than about 100 cp. This relatively thin reagent may produce the coffee ring effect described above.

Spec. ¶ 87 (cited in Decl. ¶ 6).

The Examiner gives little or no weight to these statements by the declarant reasoning that "Bateson does not disclose such a feature [of the "coffee ring" effect] and Appellants haven't provided evidence for such an effect in Bateson." Ans. 21. The Examiner further responds that

> Bateson doesn't describe any noteworthy details pertaining to the surface contour of the wet or dried reagent [and] . . . it would be

> improper to read into the disclosure of Bateson to give the surface of the reagent any particular contour without some teaching, suggestion and/or evidence to do so.

Id.

The record before us therefore shows: (1) the Examiner acknowledges "Bateson doesn't describe any noteworthy details pertaining to the surface contour of the wet or dried reagent" (*id.*), and (2) the Declaration is the only piece of evidence showing that a skilled artisan would have expected a calculation of the ratio of the thinnest and thickest parts of the dried reagent to require details such as the contour of the surface of the reagent (Decl. ¶¶ 26, 27). The record therefore supports Appellant's argument that the Examiner has not made a sufficient showing that the prior art teaches or suggests the recited ratio.

The Examiner additionally finds that the recited ratio is no more than an ordinary change in size, which is within the level of ordinary skill. Final Act. 7 (citing *In re Rose*, 220 F.2d 459, 463 (CCPA 1955), for the proposition that "the size of the article under consideration . . . is not ordinarily a matter of invention"). The evidence before us, however, supports that uniform consistency (as the recited ratio reflects) improves the sensor's function. In particular, the Specification provides that "[t]he test sensor's accuracy and precision depend on the uniform consistency of the dry reagent layer's physical and chemical composition." Spec. ¶ 5. The Specification seeks to address the "coffee ring" effect by providing improvements of "the reagent uniformity onto the base of the test sensor." Spec. ¶ 88; *see id.* ¶¶ 87, 89. The record therefore does not support the rejection for this additional reason.

CONCLUSION

The Examiner's rejections are reversed.

DECISION SUMMARY

In summary:

Claim(s) Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
31–37, 39–47, 49, 50	103	Bateson, Vreeke		31–37, 39–47, 49, 50
38, 48	103	Bateson, Vreeke, Karinka		38, 48
Overall Outcome				31–50

REVERSED