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Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

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MARTINEZ, TARA L	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BO ÅKERSTRÖM, STEFAN HANSON,
MARTIN LENNARTH OLSSON, and MAGNUS GRAM[1]

Appeal 2017-004993
Application 13/054,188
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) involving claims to a method of treating a subject using alpha-1-microglobulin (A1M). The Examiner's rejections of claims 28–31, 35–37, and 39–43 under 35 U.S.C. §§ 102(b) and 103(a) are appealed. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

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[1] The Real Party in Interest is identified as "A1M Pharma AB." Appeal Br. 3. We herein refer to the Specification of Jan. 14, 2011 ("Spec."); Final Office Action of Dec. 17, 2015 ("Final Action"); Appeal Brief of May 12, 2016 ("Appeal Br."); Examiner's Answer of Dec. 12, 2016 ("Answer"); and Reply Brief of Feb. 7, 2017 ("Reply Br."). Oral argument was heard on November 1, 2018; a transcript of the hearing will be made a part of the record on appeal.

STATEMENT OF THE CASE

Independent claim 28, reproduced below, is representative:

> 28. A method of treating a subject suffering from a disease or condition involving oxidative stress and reducing oxidant levels in a subject in need thereof, the method comprising administering to the subject an amount of alpha-1-microglobulin (A1M) effective to reduce oxidant levels in the subject of from about 0.5 mg/kg to about 100 mg/kg, wherein the disease or condition involving oxidative stress is selected from the group consisting of sepsis, inflammation, arthritis, hemolytic transfusion reaction, and diabetes.

Appeal Br. 21 (Claims Appendix). The other independent claim, claim 29, is substantially similar to claim 28, except for being directed to "reducing free haemoglobin levels in a subject" suffering from a disease or condition associated with the presence of free haemoglobin, as opposed to "reducing oxidant levels," however, both claims define the same group of "disease[s] or condition[s]" to be treated.

The following rejections are on appeal:

Claims 28, 30, 31, and 39–43 stand rejected under 35 U.S.C. § 102(b) as anticipated by Houston,[2] as evidenced by MGI.[3] Final Action 2.

Claim 29 stands rejected under 35 U.S.C. § 102(b) as anticipated by Houston, as evidenced by COLA.[4] *Id.* at 6.

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[2] US 5,166,133 (issued Nov. 24, 1992) ("Houston").
[3] MGI –Mouse Facts, http://www.informatics.jax.org/mgihome/other/ - mouse_facts1.shtml (last visited June 1, 2015) ("MGI").
[4] COLA, *Fast Facts 30, Complications of Blood Transfusion: Discussion and Investigation* (2006) ("COLA").

Claim 35 stands rejected under 35 U.S.C. § 103(a) over Houston and Sadeghi.[5] *Id.* at 15.

Claims 36 and 37 stand rejected under 35 U.S.C. § 103(a) over Houston, Sadeghi, and Terpe.[6] *Id.* at 17–18.

DISCUSSION

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. [Only once] that burden is met, the burden of coming forward with evidence or argument shifts to the applicant." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

"Anticipation requires that all of the claim elements and their limitations are shown in a single prior art reference." *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009). "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 Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). "[O]bviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

Appellants argue the anticipation rejections together, focusing on the Houston reference's alleged failings. The arguments presented by Appellants over the obviousness rejections largely overlap their anticipation arguments and they are also argued together by Appellants. Moreover, the

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[5] US 2007/0060512 A1 (published Mar. 15, 2007) ("Sadeghi").
[6] K. Terpe, *Overview of tag protein fusions: from molecular and biochemical fundamentals to commercial systems*, 60 APPL MICROBIOL BIOTECHNOL 523–33 (2003) ("Terpe").

same findings of fact are determinative for all outstanding rejections. Therefore, we address all rejections together.

The Examiner determined that claims 28, 30, 31, and 39–43 are anticipated by Houston because the reference teaches administering the claimed composition (i.e., "A1M"), at the claimed amount (i.e., 3 mg/kg, which is within the claimed "about 0.5 mg/kg to about 100 mg/kg"), to the claimed patient population (i.e., subjects needing treatment for sepsis, inflammation, arthritis, and/or hemolytic transfusion reaction), and that the physiological results of such administering, i.e., reducing oxidant levels, would inherently occur. *See* Final Action 2–15, 20–22 and Answer 2–7, 12–26 (citing Houston abstract, 1:54–58, 2:14–27, 2:41–48, 11:14–17, 11:20–68, 18:56–19:13 (Example 6, Table 8), claims 1, 5, 7; *generally* MGI (laboratory mouse "[g]eneral [b]ody weight: average - 20 g; highly variable")). Regarding claim 29, the Examiner made the same determinations concerning Houston, but also cited COLA as evidence that blood transfusions cause acute hemolytic transfusion reaction. Final Action 6. Regarding claim 35, the Examiner determined that the claim would have been obvious over the combination of Houston and Sadeghi, relying on the determinations concerning Houston set forth for the anticipation of the independent claims and adding Sadeghi for its disclosure of specific claimed A1M peptide sequences. *See* Answer 7–9. Similarly, regarding claims 36 and 37, the Examiner also relied on the determinations concerning Houston's anticipation of the independent claims, combined with Sadeghi's teachings as for claim 35, and added Terpe for its disclosure of ways to

modify A1M by adding a histidine tag and a factor X cleavage site. *Id.* at 10–11.

Appellants present a persuasive argument, which is that Houston does not disclose administering from about 0.5 mg/kg to about 100 mg/kg of A1M to a subject in need, as claimed. Appeal Br. 15–16.

Although Appellants do not contest the Examiner's math or factual determinations concerning the dosage of Houston's Example 6 (i.e., that a mouse has a mass of about 20g and administering 60 µg of a therapeutic formulation to a 20g animal results in a dose of 3 mg/kg), we note that Houston's relevant disclosure is not so straightforward. Houston's Example 6 indicates that "[f]our compositions were administered i.p. to mice: 1.5% thioglycollate (TG) alone; 1.5% thioglycollate and a peptide from the CD 18 adhesion molecule called 4-29 (as a positive control); 1.5% thioglycollate and a peptide from an oncogene called JUN (as a negative control); and 1.5% thioglycollate and α_1-M." Houston 18:56–66. Houston then discloses that this last formulation of 1.5% thioglycollate and A1M was administered to a mouse at a dose of 60 µg, which is the relevant disclosure cited by the Examiner in rejecting the claims.

The problem we find with this determination by the Examiner is that the claims require "administering to the subject *an amount of alpha-1-microglobulin (A1M)* effective to reduce oxidant levels in the subject of from about 0.5 mg/kg to about 100 mg/kg" (emphasis added), but the disclosure of Houston does not specify how much of the 60 µg administered to the mouse was actually A1M as compared to thioglycollate (or some other component). *See* Appeal Br. 21 (Claims Appendix). We find no analysis by

the Examiner that accounts for the amount of components in Houston's compositions. Thus, it is not possible to know, based on the Examiner's analysis, whether the claims are anticipated by such a disclosure or, relatedly, would have been obvious thereover. For this reason, we must find the Examiner has not established a prima facie case for either anticipation or obviousness.

SUMMARY

The anticipation and obviousness rejections are each reversed.

REVERSED