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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/641,590	10/16/2012	Yunwei Charles Cao	222106-1555	1085

24504 7590 02/13/2018

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ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
02/13/2018	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte YUNWEI CHARLES CAO, CHEN LIU, HONGYAN LIU, ZHONGLIANG WANG, and SOON HYE YANG

Appeal 2016-007263
Application 13/641,590[1]
Technology Center 1600

Before FRANCISCO C. PRATS, JOHN G. NEW, and RYAN H. FLAX, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims to a nanoparticle that has, attached to it, an enzyme and a moiety that recognizes a molecular target. The Examiner rejected the claims for obviousness.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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[1] Appellants state that the "real party in interest of the instant application is University of Florida Research Foundation, Inc. having a principle place of business at 223 Grinter Hall, Gainesville, Florida 32611." Appeal Br. 3.

STATEMENT OF THE CASE

The following rejections are before us for review:

(1) Claims 1–3, 5–9, 12–15, and 17, under 35 U.S.C. § 103(a) as being unpatentable over Farokhzad[2] (Final Act. 2–6, 9–10);

(2) Claim 4, under 35 U.S.C. § 103(a) as being unpatentable over Farokhzad and Suri[3] (*id.* at 6–7);

(3) Claim 10, under 35 U.S.C. § 103(a) as being unpatentable over Farokhzad and Grünweller[4] (*id.* at 7–8);

(4) Claim 11, under 35 U.S.C. § 103(a) as being unpatentable over Farokhzad, Grünweller, and Suri (*id.* at 8–9); and

(5) Claim 16, under 35 U.S.C. § 103(a) as being unpatentable over Farokhzad and Li[5] (*id.* at 10–11).

Claim 1, the only independent claim on appeal, reads as follows:

1. A nanozyme, comprising:

a nanoparticle having an enzyme and a plurality of recognition moieties attached thereto, and optionally having one or more protecting moieties attached thereto,

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[2] WO 2008/105773 A2 (published Sept. 4, 2008).

[3] S. Suri et al., *RNase: A Novel Enzyme For Treatment Of Cancers*, 5 THE INTERNET JOURNAL OF ONCOLOGY 1–7 (2007). (http://ispub.com/IJO/5/1/5326 (last accessed Sept. 17, 2014)).

[4] Arnold Grünweller & Roland K. Hartmann, *Locked Nucleic Acid Oligonucleotides: The Next Generation of Antisense Agents?*, 21 BIODRUGS 235–43 (2007).

[5] Chun-Qi Li & Guang-Xian Zhang, *Nanosize delivery as an emerging platform for cancer therapy*, 7 CANCER BIOLOGY & THERAPY 1860–62 (2008).

> *wherein the recognition moieties target a specific target molecule that reacts with the enzyme*, and
>
> wherein the recognition moieties and protecting moieties are at a density on the nanoparticle that substantially reduces non-target molecules from reacting with the enzyme.

Appeal Br. 18 (emphasis added).

DISCUSSION

The Examiner's Prima Facie Case

The Examiner found that Farokhzad teaches a nanoparticle for targeted delivery of therapeutic agents, the nanoparticle having attached to it both the recognition moieties and enzyme required by Appellants' claim 1. Final Action 3. Specifically, the Examiner cited Farokhzad as disclosing that its nanoparticle includes "a targeting moiety (recognition moiety) such as an antibody and a therapeutic agent such as an enzyme." *Id.* (citing Farokhzad ¶¶ 20, 24, 237, and claim 60).

As to the enzyme required by Appellants' claim 1, the Examiner found that "Farokhzad teaches that the agent to be delivered could be an enzyme (L-asparaginase, which performs a hydrolysis), which would react with the targeting molecule (proteins in cells or specifically, asparagine an amino acid in proteins in cells)." *Id.* (citing Farokhzad ¶¶ 237 and 175).

Although the Examiner found that Farokhzad differs from Appellants' claim 1 in not expressly describing its nanoparticles as having recognition and protecting moieties that meet claim 1's density requirement, the Examiner concluded, nonetheless, that nanoparticles meeting that requirement would have been obvious. *Id.* at 3–4.

Analysis

> As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):
>
> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In the present appeal, we agree with Appellants that the Examiner has not shown by a preponderance of the evidence that the nanozyme recited in claim 1 would have been obvious to an ordinary artisan.

In particular, we agree with Appellants that Farokhzad "does not teach or suggest a targeting moiety that targets asparagine, the 'specific molecule that also reacts with the enzyme' (L-asparagine) as required by instant claim 1." Appeal Br. 10.

We acknowledge, as the Examiner found, that Farokhzad teaches a "targeted particle" which may be a nanoparticle, and which includes a therapeutic agent and a "targeting moiety," the targeting moiety "target[ing] prostate cancer cells." Farokhzad, p. 102 (claims 1 and 2).

We acknowledge, as the Examiner found, that Farokhzad discloses that "[i]n some embodiments, the agent to be delivered may be an anti-cancer agent. Exemplary protein anti-cancer agents are enzymes (*e.g.*[,] L-asparaginase) . . . ." *Id.* ¶ 237.

As Appellants point out, however, claim 1 requires its recognition moieties to "target *a specific target molecule* that reacts with the enzyme." Appeal Br. 18 (emphasis added). As Appellants contend, the Examiner does not identify in Farokhzad any teaching or suggestion of a targeting moiety

that targets asparagine, which is undisputedly the specific molecule that reacts with the asparaginase enzyme.

In that regard, the Examiner contends that "Farokhzad specifically suggests that the target of the targeting molecule can comprise protein, a carbohydrate, a lipid, and/or a nucleic acid (see para. 00175), therefore implying that the target being a molecule in which the agent reacts with." Ans. 5.

We acknowledge Farokhzad's teaching that its targeting moieties may target "a protein, a carbohydrate, a lipid, and/or a nucleic acid. In certain embodiments, a target can comprise a protein and/or characteristic portion thereof, such as a tumor-marker, integrin, cell surface receptor, transmembrane protein, intercellular protein, ion channel, membrane transporter protein, enzyme, antibody, chimeric protein, glycoprotein, *etc.*" Farokhzad ¶ 175.

The Examiner, however, does not identify any disclosure in Farokhzad that teaches, suggests, or even implies, that its targeting moieties target asparagine, the specific molecule that reacts with the enzyme identified by the Examiner as teaching the enzyme element recited by Appellants' claim 1. Nor does the Examiner otherwise adequately explain why any other teaching in Farokhzad would suggest or imply that its targeting moiety targets a specific molecule that also reacts with an enzyme delivered by the nanoparticle. As noted above, for example, in claim 1 of Farokhzad cited by the Examiner, the targeting moiety targets prostate cancer *cells* (Farokhzad, p. 102), rather than a *specific molecule* with which a nanoparticle-delivered enzyme would react; contrary to statements by the Examiner, a cell is not a molecule (Answer 6).

In sum, for the reasons discussed, Appellants persuade us that the Examiner has not shown by a preponderance of the evidence that the nanozyme recited in Appellants' claim 1 would have been obvious to an ordinary artisan. We, therefore, reverse the Examiner's rejection of claim 1, and its dependent claims 2, 3, 5–9, 12–15, and 17, over Farokhzad.

As to the remaining rejections, the Examiner cited Suri, Grünweller, and Li as evidence that the additional elements recited in dependent claims 4, 10, 11, and 16 would have been obvious features of the nanozyme recited in Appellants' claim 1. Because the Examiner does not adequately explain how Suri, Grünweller, and/or Li remedy Farokhzad's deficiencies, discussed above, as to claim 1, we reverse the Examiner's rejections based on Farokhzad combined with Suri, Grünweller, and Li.

REVERSED