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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* PAUL TARDI, LAWRENCE MAYER, and  
DAVID BERMUDEZ

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Appeal 2014-008998  
Application 13/122,454  
Technology Center 1600

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Before JOHN G. NEW, RICHARD J. SMITH, and  
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

Appellants request rehearing of the decision entered September 28, 2016 (“Decision”). Appellants argue that the Decision misapprehended or overlooked certain points regarding the obviousness rejection (Rejection No. 1) and the obviousness-type double patenting rejections (Rejections Nos. 2–4). (Req. Reh’g. 2 (citing Decision 2).)

We have considered Appellants’ arguments but are not persuaded that we either misapprehended or overlooked any relevant issue of fact or law in reaching the conclusions set out in the Decision. The request for rehearing is denied.

As an initial matter, Appellants are reminded that a request for rehearing is not a vehicle to reargue or expand upon prior arguments, or merely express disagreement with the Board's decision. *See* 37 C.F.R. § 41.52 (“The request for rehearing must state with particularity the points believed to have been misapprehended or overlooked by the Board.”). In this case, all evidence and arguments presented by Appellants, including the arguments made at the hearing, were fully considered in reaching the Decision.<sup>1</sup>

The points raised by Appellants are addressed in correspondingly numbered paragraphs below. Points 1–5 relate to the obviousness rejection and points 6–8 relate to the obviousness-type double patenting rejections. (Req. Reh'g. 7.)

#### ANALYSIS

1. Appellants contend that we overlooked their argument that evidence indicating or suggesting that liposomes cannot penetrate through the “normalized” tumor vascular “could not possibly exist” because Appellants “have shown that liposomes can do so.” (Req. Reh'g. 2 (citing Reply Br. 7).) To the contrary, that argument was considered and deemed unpersuasive. The test for obviousness is what the prior art would have suggested to a person of ordinary skill in the art, *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (citing cases), not whether “concrete evidence” exists to prove that a claimed invention would not work. (Req. Reh'g. 2.) Similarly,

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<sup>1</sup> The “confirmatory evidence” dated December 2010, submitted by Appellants on October 21, 2016, is not permitted in connection with the request for rehearing. *See* 37 C.F.R. § 41.79 (b). Therefore, we do not consider it for purposes of this request for rehearing.

we did not overlook Appellants' argument that "what you would expect is that at least you would have a reduction in the effect of the liposomes."  
(Hearing Transcript 4.)

Here, the Examiner established that the claimed invention was prima facie obvious based on the prior art. Appellants' evidence and arguments were considered and were not deemed to overcome or rebut that prima facie case.<sup>2</sup> (See Decision 4–5.)

2. Appellants contend that, based on Finding of Fact 4 (Decision 3), we misapprehended the teachings of paragraph 103 of the Tardi<sup>3</sup> reference given the "context of the invention of Tardi." (Req. Reh'g. 3.) Even if that "context of the invention" argument had been raised before, it would not have been persuasive because the Tardi reference may be considered for all that it teaches. See *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012). Thus, Appellants' argument that "the combination suggested [by Tardi] has nothing to do with the critical feature of the invention" is unpersuasive. (Req. Reh'g. 3.) Accordingly, we did not misapprehend the teachings of Tardi, including paragraph 103 thereof. (See Decision 5–6.)

3. Appellants argue that we misapprehended Terstriep,<sup>4</sup> based on

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<sup>2</sup> Appellants contend that the statement "more permeable 'normalized' vasculature," quoted from the Examiner (Decision 8), should have read "less permeable 'normalized' vasculature." (Req. Reh'g. 2.) However, "normalized" vasculature is *more* permeable than "normal" vasculature and less permeable than leaky vasculature. See, e.g., Jain, *Normalizing tumor vasculature with anti-angiogenic therapy: A new paradigm for combination therapy*, 7 NATURE MEDICINE 9, 987–89 (2001) ("Jain '01"), 987, right col.

<sup>3</sup> Tardi et al., WO 2004/093795 A2, published Nov. 4, 2004 ("Tardi").

<sup>4</sup> Terstriep, *First- and second-line therapy of metastatic colorectal cancer*, Expert Rev. Anticancer Ther. 6, 921–30, Abstract (2006) ("Terstriep").

Finding of Fact 5 (Decision 4), “in the context of the invention.” (Req. Reh’g. 4.) Furthermore, Appellants contend that “[t]he irrelevance of the teachings of Terstriep, in the context of the invention which requires liposomal delivery, has been overlooked.” (Req. Reh’g. 4.) While Appellants may disagree with the application of Terstriep in combination with Tardi, we did not misapprehend the teachings of Terstriep or find it to be irrelevant (and thus did not overlook its alleged “irrelevance”).

4. Appellants contend that we dismissed Dr. Mayer’s Declaration<sup>5</sup> as “mere opinion that is not determinative,” thereby misapprehending the nature of Dr. Mayer’s testimony, as well as the nature of the holding in *In re Beattie*, 974 F.2d 1309, 1313 (Fed. Cir. 1992). (Req. Reh’g. 4–5.) In particular, Appellants argue that Dr. Mayer testified “from his own knowledge as to the general understanding in the art” and regarding the “efficacy of liposomes” in view of “the ‘leaky’ vasculature associated with solid tumors,” and that those were statements of fact, not opinions. (Req. Reh’g. 5 (citing Mayer Decl. ¶¶ 4, 5).)

We did not dismiss Dr. Mayer’s Declaration or misapprehend his testimony. On the contrary, we fully considered the statements therein as evidence, and gave those statements appropriate weight, but found that the Mayer Declaration did not “overcome or rebut the prima facie case of obviousness.” (Decision 5–7.) Moreover, we are not persuaded of any

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<sup>5</sup> Declaration of Lawrence D. Mayer under 37 C.F.R. § 1.132, dated April 30, 2013.

misapprehension regarding the nature of Dr. Mayer's testimony or the *Beattie* decision.<sup>6</sup>

5. Appellants contend that we overlooked the literature cited by Appellants, and particularly the Maeda<sup>7</sup> and Matsumura<sup>8</sup> references, because they were not cited in the Decision. (Req. Reh'g. 5–7.) In particular, Appellants contend that we overlooked “the clear understanding in the art that the EPR effect applies to liposomes.” (*Id.* at 6.) To the contrary, we did not overlook the literature cited by Appellants or Appellants' position that the EPR effect applies to liposomes. (*See* Decision 5–9.) Moreover,

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<sup>6</sup> Appellants contend that our citation to *Beattie* was inapt because the declarations in *Beattie* “were relied on for their legal conclusion that the invention would not have been obvious, rather than providing any factual evidence.” (Req. Reh'g. 4.) However, *Beattie* indicates that, among other statements, the declarations “opine that [the prior art] teaches away from the claimed invention.” *Beattie*, 974 F.2d at 1313. Whether a reference teaches away from a claimed invention is a question of fact. *Mouffet*, 686 F.3d at 1333.

<sup>7</sup> Maeda et al., *Mechanism of tumor-targeted delivery of macromolecular drugs, including the EPR effect in solid tumor and clinical overview of the prototype polymer drug SMANCS*, JOURNAL OF CONTROLLED RELEASE, 74, 47–61 (2001); Maeda, et al., *Polymeric drugs for efficient tumor-targeted drug delivery based on EPR-effect*, EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS 71, 409–19 (2009).

<sup>8</sup> Matsumura et al., *A New Concept for Macromolecular Therapeutics in Cancer Chemotherapy: Mechanism of Tumoritropic Accumulation of Proteins and the Antitumor Agent Smancs*, 46 CANCER RESEARCH 6387–92 (1986).

contrary to Appellants' contention, Appellants' arguments regarding Jain '01, Tong,<sup>9</sup> and Kerbel<sup>10</sup> were considered. (*Id.* at 8.)

6. Appellants contend that Finding of Fact 6 regarding Flowers<sup>11</sup> overlooks the point that “[t]here is no need for the antiangiogenic agents to enter the interstices of the solid tumor,” but that “chemotherapeutic agents . . . must be introduced into the tumor.” (Req. Reh’g. 7.) Flowers was applied in the obviousness-type double patenting rejections for its teaching of adding a VEGF inhibitor. (*See* Decision 9–10.) Accordingly, we did not overlook the point asserted by Appellants.

7. Appellants argue that the Decision “overlooks the irrelevance of the Flowers disclosure.” (Req. Reh’g. 8.) To the contrary, Flowers was properly considered in connection with the obviousness-type double patenting rejections, and Flowers was not found to be irrelevant. (*See* Decision 9–10.) Moreover, Appellants’ discussion of “accidental anticipation” (Req. Reh’g. 9) is not pertinent to the basis for which Flowers was applied in the obviousness-type double patenting rejections.

8. Appellants argue that the statement “we discern no error in the Examiner’s finding that the claims are not patentably distinguishable from the teachings of Flowers. (Ans. 18–19.)” (Decision 10) constitutes a new ground of rejection. (Req. Reh’g. 9–10.) When read in the context of

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<sup>9</sup> Tong, et al., *Vascular Normalization by Vascular Endothelial Growth Factor Receptor 2 Blockade Induces a Pressure Gradient Across the Vasculature and Improves Drug Penetration in Tumors*, *CANCER RESEARCH* 64, 3731–36 (2004).

<sup>10</sup> Kerbel, *Antiangiogenic Therapy: A Universal Chemosensitization Strategy for Cancer?* *SCIENCE* 312, 1171–75 (2006).

<sup>11</sup> Flowers et al., US 2003/0082228 A1, published May 1, 2003 (“Flowers”).

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Appellants' argument regarding the scope of the claims and the cited pages of the Examiner's Answer, it is clear that the sentence does not constitute a new ground of rejection. As the record shows, the obviousness-type double patenting rejections were based on the respective patent claims in view of Flowers, rather than Flowers alone, and Appellants had a fair opportunity to respond to those rejections. *See In re Kronig*, 539 F.2d 1300, 1302 (CCPA 1976) (“[T]he ultimate criterion of whether a rejection is considered ‘new’ in a decision by the board is whether appellants have had fair opportunity to react to the thrust of the rejection.”)

#### CONCLUSION

Appellants have not shown that we misapprehended or overlooked any issue of law or fact in the Decision. The request for rehearing is denied.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

REHEARING DENIED