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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HARITHA SAMARANAYAKE, JERE PIKKARAINEN, ANN-MARIE MAATTA, and SEPPO YLA-HERTTUALA

Appeal 2017-003624[1]
Application 13/858,393
Technology Center 1600

Before RICHARD M. LEBOVITZ, DEVON ZASTROW NEWMAN, and DAVID COTTA, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

This is a decision on Appellant's Request for Rehearing ("Req. Reh'g") under 37 C.F.R. § 41.52(a)(1) of the Decision on Appeal, entered Nov. 13, 2017 ("DOA"). The appeal involved claims directed to a viral vector, ganciclovir, and temozolomide for treating malignant glioma. Appellants request reconsideration of the Decision on Appeal to affirm the Examiner's rejection of claims 1–14, 17–25, 27–32, and 34–40 as obvious in view of Medical News, Yla-Herttuala, Wick, and Rainov.

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[1] The Appeal Brief ("Appeal Br.") identifies Fin Vector Therapies Ltd, as the real party in interest. Appeal Br. 2.

The Request for Rehearing states that the Board erred in finding that synergy between ganciclovir and temozolomide "is an unnecessary red herring." Req. Reh'g 2.

To support this argument, Appellants cite evidence not relied upon in the Appeal Brief or Reply Brief that temozolomide damages DNA and causes myelosuppression. *Id.* at 2–3. It is procedural error to raise new evidence in a Request for Rehearing absent a qualifying exception:

> Arguments not raised, and Evidence not previously relied upon, pursuant to §§ 41.37, 41.41, or 41.47 are not permitted in the request for rehearing except as permitted by paragraphs (a)(2) through (a)(4) of this section.

37 C.F.R. § 41.52(a)(1). Appellants did not establish that any of the exceptions for new evidence or arguments apply. Consequently, the new evidence shall not be considered.

Appellants reiterate their argument already addressed in the Decision on Appeal that Rainov did not show synergy or an added benefit of utilizing a combination of temozolomide and ganciclovir *in vivo*. Req. Reh'g 4. Appellants also argue:

> Rainov cogently demonstrates why a physician would avoid adding Wick's temozolomide to Yla-Herttuala's ganciclovir *in vivo*.
>
> The Decision on Appeal correctly notes that in contrast to his in vivo data, Rainov's in vitro data show synergy. This is correct, but irrelevant. The instant claims require "a human." Rainov may well render obvious claims to an in vitro diagnostic, but Rainov's in vivo data clearly and cogently show why the artisan would avoid adding Wick's temozolomide to Yla-Herttuala's ganciclovir to treat a human patient *in vivo*.

Req. Reh'g 4.

To begin, the rejection is not based on "adding Wick's temozolomide to Yla-Herttualas's ganciclovir to treat a human patient *in vivo*" as stated in the Request for Rehearing. *Id.* The Decision on Appeal expressly found that Medical News disclosed treating patients with both temozolomide and ganciclovir. DOA 11. Rainov was also cited for teaching "administering HSV-tk, ganciclovir, and temozolomide on malignant glioma." *Id.* Wick and Yla-Herttuala were cited for teaching specific dosages and regimens of temozolomide and ganciclovir. *Id.* Thus, Appellants' statement about the basis of the rejection is not correct. Rather, the rejection is based on prior art teachings that used all three elements of the claim to treat tumors.

The reason the Decision on Appeal described the discussion of synergy in Rainov as a red herring[2] was because Appellants argued, as they do in this Request for Rehearing, that "Rainov . . . teach[es] ***avoiding*** the combination [of temozolomide and ganciclovir] because it would increase risk and provide no off-setting benefit." Appeal Br. 22. However, contrary to this argument, these two drugs were not only administered together to treat tumors in Rainov and Medical News, but found to be advantageous in combination. The following passages from Rainov and Medical News were cited in the Decision on Appeal to support this conclusion:

> Summarizing our data, the demonstration of synergy between *HSV- tk/* GCV [ganciclovir] gene therapy and chemotherapy with TMZ [temozolomide] suggests a possible enhanced therapeutic concept for future studies in human malignant glioma. Despite many still unknown variables, the present results were clearly defined in a glioma cell culture system and

[2] "[S]omething that distracts attention from the real issue." https://www.merriam-webster.com/dictionary/red%20herring (last accessed January 1, 2018).

> confirmed in animal experiments, and therefore justify further investigation.

Rainov 667.

> On the primary endpoint, the group given Cerepro (R) and temozolomide showed an improvement of 68% in median survival time compared with standard care surgery and radiotherapy controls (350 days vs 208 days). Against the same controls, treatment with Cerepro (R) alone showed an improved median survival trend approaching 50%, similar to those given treatment with temozolomide alone after surgery and radiotherapy (300 days and 307 days respectively vs 208 days with standard care). Improvements in the combined Cerepro (R) [to clarify for Appellants, the use of Cerepro means the viral vector HSV-tk and GCV because the purpose of the vector is to convert GCV into an active drug] and temozolomide treatment group (n= 58) and temozolomide alone group (n=76) were significant ($p<0.05$).

Medical News 2.

Thus, each of Rainov and Medical News *actually* used the same claimed combination of viral vector, temozolomide and ganciclovir. These publications did not discourage nor disparage the results obtained with the combination, but rather stated "further investigation" was justified (Rainov 667) and "[i]mprovements . . . were significant." Medical News 2.

Despite these clear statements in Rainov and Medical News, Appellants contend that a skilled worker would have been discouraged from using the two drugs together because no benefit was observed. Req. Reh'g 3. In other words, Appellants contend that the skilled worker would have disregarded the plain teachings in Medical News and Rainov. We were not persuaded by this argument in the Appeal Brief, and still are not by the Request for Rehearing.

Specifically, Appellants have not provided persuasive objective evidence that one of ordinary skill in the art would have ignored Rainov's teaching of synergy and Medical News's teaching of improvement when the two drugs were utilized to treat humans. Appellants ask us to disregard these explicit teachings in which all three elements of the claim were utilized (viral vector, ganciclovir, and temozolomide) without providing objective evidence to support their argument, such as a declaration by one of ordinary skill in the art, experimental results, or rebuttal evidence. An argument made by counsel in a brief does not substitute for evidence lacking in the record. *Estee Lauder, Inc. v. L'Oréal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997).

We do not agree that "synergy" is essential in analyzing non-obviousness as argued by Appellants (Req. Reh'g 3) because Medical News teaches that the use of the claimed adenoviral vector, ganciclovir, and temozolomide showed an improvement of 68% in median survival time in contrast to "approaching 50%" when the vector or drug was used alone:

> On the primary endpoint, the group given Cerepro (R) [the adenoviral vector and ganciclovir] and temozolomide showed an improvement of 68% in median survival time compared with standard care surgery and radiotherapy controls (350 days vs 208 days). Against the same controls, treatment with Cerepro (R) alone showed an improved median survival trend approaching 50%, similar to those given treatment with temozolomide alone after surgery and radiotherapy (300 days and 307 days respectively vs 208 days with standard care).

Medical News 2 (emphasis added) (quoted from DOA 19). Whether the improvement is synergistic or simply an additive effect is irrelevant. Median survival time is better when both therapies are used in combination,

so why would the medical practitioner avoid the benefits of the combination as argued by Appellants? Req. Reh'g 4.

Accordingly, while we have considered Appellants' Request for Rehearing of the Decision on Appeal, we decline to modify it.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

REHEARING DENIED