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PTAB Declines Request to Review Method of Treating Lymphoma Claim

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In rejecting petitioner's anticipation and obviousness challenges, the panel found that several asserted references were not publicly accessible and, therefore, did not qualify as "printed publications." First, although a clinical study consent form was distributed to approximately 40 prospective patients, there was no evidence that it was distributed to *ordinarily skilled artisans*, rather than patients. There was also no evidence to show that an interested party would have known to visit a particular oncology website to look for the consent form. Second, although petitioner's expert testified that a clinical study protocol was "freely disseminated to any referring doctor or patient," the panel found this testimony insufficient to establish public accessibility because the expert "[did] not identify any particular instances or the timeframe of its dissemination." Finally, the panel held that petitioner failed to show that the rituximab label was publicly accessible. In rejecting petitioner's assertion that the rituximab label was made publicly accessible "when Rituxan was approved," the panel explained that petitioner failed to provide any documentary or testimonial evidence showing that the label was included in the packaging of a disseminated drug product.

The panel also rejected petitioner's obviousness challenge because it found that the asserted references failed to disclose the particular treatment regimen and dosing amount limitations recited in the challenged claim. In reaching its decision, the panel rejected the assertion that a skilled artisan would have sought to treat low grade non-Hodgkin's lymphoma patients with the same dosing regimen employed in a study of a wholly different patient population – namely, *elderly patients* having *aggressive* non-Hodgkin's lymphoma. Nor did petitioner sufficiently explain why an ordinarily skilled artisan would have usedarituximab dose of 375

mg/m^2, given the reference's teachings that "doses up to 500 mg/m^2" had been used and that "the best dose and schedule of rituximab remain to be established."

Celltrion, Inc. v. Biogen, Inc., IPR2017-01093 (PTAB October 6, 2017)
[Franklin, Snedden, Harlow (opinion)]

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