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Axinn IP Update: Six Patents Directed to Humanized Monoclonal Antibodies Fall at PTAB

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Axinn Update

Although it has been relatively uncommon for patent claims directed to humanized monoclonal antibodies to be invalidated as obvious, the Patent Trial and Appeal Board piqued the interest of the biosimilar community last week when it did just that. Eli Lilly brought six petitions asserting that claims in six patents were invalid as obvious.[1] In two Final Written Decisions, the PTAB found that Eli Lilly made a persuasive case for obviousness on all challenged claims. In doing so, the PTAB declined to give substantial weight to the patent owner's evidence of secondary considerations, in part because the PTAB determined that the patent owner failed to establish a nexus between the challenged claims and the anti-CGRP antibodies put forth by the patent owner as evidence of secondary considerations (industry praise, long-felt need, unexpected results, industry skepticism, commercial success, and licensing).

Eli Lilly argued that the claims were obvious over a combination of three, or alternatively four, prior art references. The patent owner cited safety concerns to support arguments that a person of ordinary skill in the art would lack a motivation to combine the prior art references, and that the prior art references taught away from such combinations. The PTAB disagreed, finding that the patent owner relied on references discussing "potential" side effects, whereas Eli Lilly cited actual studies showing few adverse events or side effects.

In response to Eli Lilly's case of obviousness, the patent owner further presented evidence of secondary considerations that the PTAB rejected for three reasons. First, the PTAB held that patent owner did not explain in its briefs how the antibodies relied on for secondary considerations were covered by the claims. Instead, the patent owner relied on a claim chart in a declaration, which the PTAB held to be an inappropriate incorporation by reference of a declaration into a brief. Second, although the PTAB held that the briefing was deficient, in the alternative, the PTAB accepted Eli Lilly's argument that the antibodies relied on for secondary considerations each possessed one or more features absent from the challenged claims. Because those features materially impacted the functionality of the antibodies, the PTAB found that there was no nexus between the products and the challenged claims. Third, the PTAB determined that even were such nexus to exist, the secondary considerations evidence was entitled to little, if any, weight.

The PTAB's decision makes clear that the door is not closed on obviousness challenges to biologic patents. If parties put forward a properly constructed argument, even one with more than two prior art references, the PTAB will give the argument the attention it deserves. But patent owners can also take a lesson from this decision by ensuring to establish a nexus between the challenged claims and any objective indicia of nonobviousness. Of course, the appeal that we are likely to see may shed further light on IPR strategies for biologic patents.

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[1] *Eli Lilly & Co. v. Teva Pharm. Int'l, GmbH*, IPR2018-01422, IPR2018-01423, IPR2018-01424, IPR2018-01425, IPR2018-01426, and IPR2018-01427, regarding U.S. Pat. Nos. 9,340,614, 9,266,951, 9,346,881, 9,890,210, 9,890,211, and 8,597,649, respectively.

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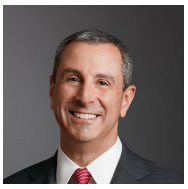

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