PTAB Denies Amgen's IPR in Win for AbbVie – Article "Suggests a High Degree of *Un*predictability" in the Art at Time of Invention

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February 4, 2016 — The Patent Trial and Appeal Board recently denied institution of Amgen's *inter partes* review against an AbbVie patent covering HUMIRA® (currently, the best-selling drug in the world).

IPR2015-01514 – *Amgen, Inc. v. AbbVie Biotechnology Ltd.* (Paper 9)[1]

In its Preliminary Response (Paper 8), AbbVie stated that the patent at issue, U.S. 8,916,157, covers HUMIRA®. In reaching its decision to deny institution, the PTAB first construed two claim phrases. The PTAB then performed an obviousness analysis, and agreed with AbbVie that an article cited by both parties (the "Wang article") "suggests a high degree of *un*predictability in the antibody formulation art." A key takeaway from this case is that a patent challenger needs to rely on references that provide more than just general guidance, and do not underscore the unpredictability of the undertaking.

The PTAB found that the term "stable" as used in the preambles of the independent claims (1 and 24) " breathes life and meaning into [the claims], and, therefore, limits [their] scope." The PTAB also agreed with AbbVie that one of skill in the art "would have understood that a formulation would need to be stable for storage and use." The PTAB also found that "a more

[1] The PTAB did a similar analysis and also denied institution of Amgen's IPR2015-01517 against AbbVie's U.S. 8,916,158.

specific threshold is unnecessary to understand the broadest reasonable interpretation of 'stable' with sufficient clarity to further analyze the claims in light of the cited prior art."

The PTAB then construed the term "a human IgG1 anti-human Tumor Necrosis Factor (TNFα) antibody, or an antigen-binding portion thereof, … wherein the antibody comprises the light chain variable region and the heavy chain variable region of D2E7." The PTAB disagreed with AbbVie's asserted construction, and found that "the broadest reasonable interpretation of the entire phrase allows for *either* an antibody comprising the light chain variable region and the heavy chain variable region D2E7, *or* one or more fragments of D2E7 that retain the ability to specifically bind TNFα."

In its obviousness analysis, the PTAB noted that both parties cited the Wang article as evidence of the state of the art at the time of invention. The PTAB also noted that the Wang article begins: "One of the most challenging tasks in the development of protein pharmaceuticals is to deal with physical and chemical instabilities of proteins." Amgen asserted that the Wang article "teaches *all* of the excipient components recited in the challenged claims …, and *how* to optimize those features to develop a stable formulation." Amgen did not, however, quote or cite specific portions of the Wang article for this proposition. Instead, Amgen relied on further discussion in the declaration of its expert (Randolph).

AbbVie responded that the Wang article demonstrates unpredictability in the art of formulating proteins, quoting the Wang article: "'[v]ery often, proteins have to be evaluated individually and stabilized on a trial-and-error basis.'" Moreover, AbbVie pointed to Amgen's prior reliance on the Wang article as evidence of unpredictability in the art during prosecution of Amgen's own protein formulation patent applications, as well as to Randolph's prior published statements regarding the complexities of protein folding and instability.

Upon consideration of the arguments and evidence, the PTAB was not persuaded that the prior art provided sufficient guidance such that a skilled artisan would have had a reasonable expectation of success in arriving at the formulation of stable, liquid pharmaceutical compositions as claimed.

Thus, AbbVie was able to stop an IPR attempted by Amgen before it was instituted. Restricted by IPR rules against submitting its own expert declaration in its preliminary response to Amgen's petition, and restricted against new evidence in general, AbbVie nevertheless was able to present an effective argument. It argued both from the petition-cited reference itself, and "old," not new, evidence in the form of Amgen's own past patent applications and Amgen's expert's own past published statement.

Effective use of available evidence by the patent owner, by effective research in the preliminary response period, to locate any and all available and persuasive evidence, such as from the petitioner's own prosecution files, and the petitioner's expert's past publications, is another key takeaway. The petitioner anticipating such a take-down effort and preparing a petition that will survive it is another.

The Leahy-Smith America Invents Act established new patent post-issuance proceedings, including the inter partes review, post grant review and transitional program for covered business method patents, that offer a less costly, streamlined alternative to district court litigation. With the U.S. Patent and Trademark Office's Patent Trial and Appeal Board conducting a large and increasing number of these proceedings, and with the law developing rapidly, Banner & Witcoff will offer weekly summaries of the board's significant decisions and subsequent appeals at the U.S. Court of Appeals for the Federal Circuit.

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