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Factual Findings Required to Show "Apparent Reason to Combine" in Patent Litigation

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Addressing issues of obviousness and anticipation in the context of an *inter partes* review, the US Court of Appeals for the Federal Circuit issued two decisions with respect to the same patent, vacating and remanding the ***Patent Trial and Appeal Board's (PTAB's)*** decision finding the claims invalid as obvious in the first case, and affirming the PTAB's finding that the claims were not anticipated in the second case. ***Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center v. Eli Lilly and Co.***, Case No. 16-1518 (Fed. Cir., Feb. 28, 2017) (Bryson, J) (Newman, J, concurring in part, dissenting from the judgment); ***Eli Lilly and Co. v. Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center***, Case No. 16-1547 (Fed. Cir., Feb. 28, 2017) (Bryson, J).

The patent at issue relates to a method of "arresting or regressing" a condition known as penile fibrosis by long-term daily administration of drugs known as type 5 phosphodiesterase (PDE5) inhibitors. Penile fibrosis includes two conditions, penile tunical fibrosis and corporal tissue fibrosis, each of which can cause erectile dysfunction, although they do not always do so. Los Angeles Biomedical Research Institute (LAB) sued Eli Lilly, alleging induced infringement of its patent by Eli Lilly's marketing of the drug Cialis, a PDE5 inhibitor. Eli Lilly subsequently filed a petition for *inter partes* review, contending that all claims of the patent were obvious in light of three prior art references. The PTAB ultimately concluded that the challenged claims were obvious because the combination of references satisfied each limitation of the challenged claims as construed and, further, because the combination provided a reasonable expectation of success in treating erectile dysfunction. LAB appealed.

The Federal Circuit agreed with LAB's contention that the PTAB's findings were insufficient to establish obviousness under the correct claim construction. Specifically, the Court found that, while the PTAB concluded that the prior art references rendered obvious the treatment of erectile dysfunction via the claimed method, it did not make factual findings to determine whether those references showed it would have been obvious to use long-term continuous treatment with a PDE5 inhibitor to treat individuals with penile fibrosis and to achieve the arrest or regression of that condition. The Court noted that the correct construction of the pertinent claim language required more than simply treating erectile dysfunction. The Court also noted that the PTAB failed to consider the possibility that, even if the combination of prior art references taught long-term treatment with a PDE inhibitor of individuals with some forms of erectile dysfunction, a person of skill in the art may not

have been motivated to combine those same references to treat individuals with fibrosis-related erectile dysfunction, for whom, LAB argued, the results would have been expected to be detrimental.

The Federal Circuit remanded the case back to the PTAB to make factual findings as to whether there was an apparent reason to combine the prior art references to treat penile fibrosis and whether a person of skill in the art would have had a reasonable expectation of success from such a combination. The Court also remanded for the PTAB to make factual findings bearing on the obviousness of the "arresting or regressing" limitation, including consideration of inventor statements during prosecution that administration for 45 days of an extremely high dose of sildenafil (PDE5 inhibitor) was required to achieve the arrest or regression of penile fibrosis.

Judge Newman dissented, stating that she would affirm the PTAB's decision. According to Newman, there was no reversible error in the PTAB's decision, and the PTAB's findings were supported by substantial evidence. With respect to the majority's remand back to the PTAB, Newman noted that "such further proceedings fail the policy and purpose of the America Invents Act, and should be invoked only when there are major defects in the PTAB proceeding requiring activity and redetermination that is not available on the appellate record." She also explained that, in this case, finality was available, and it was the Court's obligation to decide the merits because "the issues were fully developed, with eloquent argument all around, [along with] an extensive Board opinion."

In the companion case, the Federal Circuit affirmed the PTAB decision finding that the challenged claims were not anticipated. The companion case related to a separate *inter partes* review petition by Eli Lilly contending that all claims of the same patent were anticipated. The PTAB instituted on the petition but ultimately concluded that the prior art did not anticipate the claims because it did not disclose a limitation requiring administration of a PDE5 inhibitor "at a dosage up to 1.5 mg/kg/day for not less than 45 days." On appeal, Eli Lilly argued that the prior art's definition of "chronic administration" anticipated the claimed requirement of daily administration for 45 days or more because a person of skill in the art would understand that erectile dysfunction (in the absence of therapy) can last longer than 45 days. The Federal Circuit was not persuaded, noting that Lilly's argument was "at best, [ ] an obviousness argument." According to the Court, substantial evidence supported the PTAB's finding that the prior art did not disclose the claimed treatment regimen "with sufficient clarity to satisfy the demanding standard for anticipation."

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