LOS ANGELES BIOMEDICAL RESEARCH INSTITUTE AT HARBOR-UCLA MEDICAL CENTER v. ELI LILLY AND COMPANY, Appeal No. 2016-1518 (Fed. Cir. February 28, 2017). Before Newman, Bryson, and Moore. Appealed from Patent Trial and Appeal Board.

Background:

LA BioMed owns a patent directed to a method for arresting or regressing penile fibrosis involving the long-term administration of PDE5 inhibitors. PDE5 inhibitors include well-known erectile dysfunction treatments, such as sildenafil (Viagra) and tadalafil (Cialis). Penile fibrosis can, but does not always, result in erectile dysfunction; and erectile dysfunction has causes other than penile fibrosis.

LA BioMed sued Eli Lilly alleging that Eli Lilly's marketing of Cialis induced infringement of its patent. Eli Lilly petitioned for *inter partes* review of the patent at the PTAB, alleging that the patent claims were unpatentable as obvious over three references. The PTAB instituted IPR, and found that LA BioMed's patent would have been obvious based on teachings in the three references that PDE5 inhibitors can be used to treat erectile dysfunction.

Issue/Holding:

Did the PTAB err in finding the patent invalid for obviousness? Yes, vacated and remanded.

Discussion:

In a 2-to-1 decision, the Federal Circuit found the PTAB's obviousness finding to be improper because it was based on an overly broad claim construction. In particular, the PTAB construed claim language relating to administration of a PDE5 inhibitor to an individual with penile fibrosis as including administration of the drug to individuals that have symptoms associated with penile fibrosis, such as erectile dysfunction, but do not necessarily have penile fibrosis. As a result of the PTAB's construction, the majority opined that the claimed method would be applicable to individuals with erectile dysfunction not caused by penile fibrosis, whereas the patent claims should be construed based on their plain meaning as administering the drug to an individual with penile fibrosis regardless of whether it results in erectile dysfunction.

The Federal Circuit also rejected the PTAB's conclusion that the limitation "arresting or regressing [penile fibrosis]" is merely a statement of intended results and is entitled to no patentable weight. The Federal Circuit based this determination on the placement of the limitation in the body of the claim as a positive method step, and not as part of the preamble, as well as intrinsic evidence in the specification, including examples of efficacy.

Because the PTAB's finding of obviousness was predicated on improper claim construction, the Federal Circuit vacated the judgment and remanded. Specifically, the PTAB's conclusion of obviousness was based on the finding that it would have been obvious to have combined the teachings of the three references to arrive at a method for treating erectile dysfunction. However, the PTAB did not make sufficient findings that those references taught long-term, continuous administration of a PDE5 inhibitor to a patient with penile fibrosis or gave rise to a reasonable expectation of success for treating penile fibrosis.

Although she agreed with the majority's discussion of claim construction, Judge Newman dissented from the judgment, arguing that the PTAB's obviousness finding was correct. Judge Newman also asserted that remand was improper and contrary to the IPR provisions of the AIA.