Any new rule or pilot program by the United States Patent and Trademark Office ("USPTO") is important to both prospective petitioners and patent owners because both parties should consider all available options when appearing in a proceeding before the Board. In three Inter Partes Review ("IPR") proceedings for Mylan Pharmaceuticals, Inc. v. Sanofi-Aventis Deutschland GmbH, the Patent Trial and Appeal Board has issued its first guidance under its motion to amend ("MTA") pilot program.[1] This new, optional program, which went into effect in March 2019, provides a patent owner two options not previously available: first, the patent owner may seek preliminary, non-binding guidance from the Board regarding its motion to amend patent claims; second, the patent owner may then revise its motion to amend based on the petitioner's opposition and the Board's preliminary guidance.[2]

In its first Preliminary Guidance (issued in three separate papers for the three IPRs), the Board addressed the burden of the patent owner—Sanofi-Aventis Deutschland gmBH ("Sanofi")—to show a reasonable likelihood that its MTA satisfied the statutory and regulatory requirements, as well as the burden of the petitioner—Mylan Pharmaceuticals, Inc. ("Mylan")—to demonstrate a reasonable likelihood that the proposed substitute claims are unpatentable.[3] Specifically, across all three IPRs, the Board found that Sanofi demonstrated a reasonable likelihood that it satisfied the statutory and regulatory requirements associated with the MTA. First, Sanofi submitted a reasonable number of substitute claims, e.g., no more than one substitute claim for each challenged claim. Further, the proposed substitute claims responded to a ground of unpatentability in the trial, did not enlarge the scope of the claims, and did not add new subject matter.

However, as indicated above, the Board also addressed Mylan's burden to demonstrate a reasonable likelihood that the proposed substitute claims are unpatentable. Specifically, in each IPR, the proposed substitute claims were rendered obvious by various combinations of prior art. Notably, the Board rejected both the petitioner's and the patent owner's attempts to incorporate by reference arguments from other papers into the opposition and MTA, respectively. Although the Board found that there is a reasonable likelihood that the proposed substitute claims would be unpatentable based on obviousness, the Board also held that, on the record available, the petitioner failed to show that the proposed substitute claims were indefinite based on the terms "the body" or the "arc shaped body."

In response to this Preliminary Guidance, Sanofi may choose to file a revised MTA, where new

substitute claims would replace those claims from the original MTA. The final written decision by the Board would address the newly proposed substitute claims in the revised MTA rather previously proposed claims from the original MTA. Nonetheless, patent owners, generally, may look to this first Preliminary Guidance from the Board for direction with their own MTA claims.

The MTA pilot program is expected to be reassessed by the USPTO in March 2020.[4]