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Federal Circuit: Preliminary Means Preliminary

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The Federal Circuit recently held that the Patent Trial and Appeal Board (PTAB) was within its discretion to reach different conclusions in a Final Written Decision (FWD) than those provided in preliminary guidance regarding the patentability of amended claims. This discretion is rooted in the different standards applied at different stages of case progress, along with the development of a mature record throughout the case.

Background

Patent Owner Medytox appealed the FWD of a post-grant review in which the PTAB found that Medytox's amended claims—made as non-contingent substitutes[1] for the originals—unpatentable for *inter alia* lack of enablement. The claims were amended as part of the Pilot Program Concerning Motion to Amend Practice and Procedures, which allows Patent Owners to request preliminary guidance from the PTAB when filing a motion to amend (MTA) and the option to file a revised MTA in response to that guidance, as well as any opposition from the Petitioner.[2] In its preliminary guidance, the PTAB stated its view that Medytox's proposed amendment to the "responder rate" limitation did not add new matter.

Based on the PTAB's preliminary guidance, Medytox filed a second non-contingent MTA that proposed revised substitute claims in place of the first set of substitutes. This second set of claims responded to the preliminary guidance, retaining limitations for which the PTAB indicated it favored the Medytox's argument; and incorporating additional limitations where the PTAB appeared to side with the Petitioner, such as narrowing genus claims to species recited in the specification. Because the PTAB's preliminary determination was non-binding,

the parties reargued their positions to the PTAB. In its FWD, the PTAB found that the substitute claims failed to meet the requirements for a motion to amend and the substitute claims were not adequately enabled. In so doing, the PTAB departed from aspects of its preliminary guidance.

On appeal, Medytox argued the PTAB's change in views regarding the amended claims violated due process and the Administrative Procedure Act (APA). Medytox also appealed the PTAB's patentability determination.

Analysis

Due to the differences between the points in a proceeding at which preliminary guidance and an FWD are decided, the Federal Circuit held that the PTAB was free to revise or reverse course from its preliminary guidance in a FWD. In the Pilot Program Concerning Motion to Amend Practice and Procedures, the PTAB reviews claims under a reasonable likelihood to succeed standard based on the record at the time. The preliminary guidance is the PTAB's estimation of whether a particular amendment might succeed, but that guidance is provided without the benefit of a fully developed record. In contrast, the PTAB's FWD is based on the entire evidentiary record reviewed under a preponderance standard. Because the PTAB applies different standards on different records at each point, the Federal Circuit reasoned the PTAB should be able to modify guidance issued in preliminary determinations in its FWD. Binding the Board to a preliminary view based on a partial record would undermine the Board's ability to properly adjudicate and could give rise to determinations that are unsupported by the record.

Further, as noted in the Federal Circuit's decision, the Pilot Program Concerning Motion to Amend Practice and Procedures makes abundant reference to the preliminary guidance being "initial," "preliminary" and "non-binding." Thus, parties seeking such guidance are informed that it is non-final.

Implications

Parties should keep in mind that preliminary guidance and other non-binding determinations may be reviewed in the PTAB's FWD. As a result, the theories presented therein must be borne out. And because the PTAB's views stated in such materials are subject to modification based on the complete record, care must be taken to ensure that the final record adequately supports a party's position.

1 A patent owner may make an MTA contingent, so that the substitute claims are only evaluated if the original claims are determined to be unpatentable; or non-contingent, which effectively cancels the original claims and requests evaluation of the replacement substitute claims.

2 Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019).

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