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Stanford University's Loss in Interferences of Three Patents Covering Testing Methods for Fetal Aneuploidies for Lack of Written Description is Vacated

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The Board of Trustees of the Leland Stanford Junior University v. The Chinese University of Hong Kong, Jun. 27, 2017, Before O'Malley, Reyna, and Chen.

Takeaway:

- The Federal Circuit declined to reconsider its decision in *Biogen MA, Inc. v. Japanese Found. for Cancer Research*, 785 F.3d 648 (Fed. Cir. 2015) that parties cannot bring civil actions in district court under 35 U.S.C. § 146 for review of the PTAB's decisions in interferences declared on or after September 16, 2012.
- In evaluating whether a claim satisfies the written description requirement, the fact finder may consider what a person of ordinary skill in the art would understand from a description of a product or technique in the specification as of the filing date of the application. Post-filing date publications may only be used as evidence of the state of the art existing on the filing date.

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Procedural Posture:

Stanford University ("Stanford") appealed from orders of the PTAB in three interference proceedings between Stanford and Chinese University of Hong Kong ("CUHK"), which found the claims of three Stanford patents directed to testing methods for fetal aneuploidies unpatenable for lack of written description. The appeal was initially filed pursuant to 35 U.S.C. § 146 in the District Court for the Northern District of California, and the parties engaged in discovery there. On May 7, 2015, the Federal Circuit affirmed the lower court's decision in *Biogen MA, Inc. v. Japanese Found. for Cancer Research*, 785 F.3d 648 (Fed. Cir. 2015), holding that under the AIA, for interferences declared after September 15, 2012, an appeal from an interference decision has to be made to the Federal Circuit. The parties then jointly requested transfer from the Northern District of California to the Federal Circuit, which was granted. The Federal Circuit considered the case on the merits, vacated and remanded.

Interference:

- The Federal Circuit declined to revisit its holding in *Biogen*, noting that although Stanford briefed this issue in its opening brief, Stanford did not raise this issue again in its reply brief or in oral argument. Rehearing *en banc* and a petition for certiorari in the *Biogen* case were denied; thus, in the Federal Circuit's view, "*Biogen* is the law in this circuit and we, as a panel, will not revisit it."
- The Federal Circuit declined to consider the record developed during discovery in the district court. Because the district court lacked subject matter jurisdiction to review the interference decisions, the Federal Circuit agreed with CUHK's position that the activities in the district court were a nullity and should

not be considered by the Federal Circuit or remanded to the Board for consideration.

Written Description:

- Sufficiency of written description is evaluated from the perspective of one of ordinary skill in the art at the time of the invention, "by examining the record evidence as to pre-filing date art-related facts." The post-filing date publications may be considered to the extent they "contain art-related facts … existing on the filing date," but may not be used as a source for the knowledge about art-related facts that did not exist on the filing date.
- The Board awarded patents in interferences to CUHK because it found that the Stanford patents' specification disclosed "targeted" rather than "random" sequencing, and the specification would not have indicated to one of ordinary skill in the art that Stanford's inventor Dr. Quake was in possession of the claimed random massively parallel sequencing ("MPS") method. The Federal Circuit held that the PTAB erred because it did not adequately explain why the Illumina platform for sequencing DNA, referenced and described in Stanford's original application, did not provide sufficient written description support for random sequencing. The Board improperly relied on the testimony of CUHK's expert, who only described that an earlier sequencing technique, Roche 454, was used for targeted sequencing, and "failed to cite to the Roche 454 references with specificity." The Board also erred in finding that, because Stanford's application *did not preclude* targeted MPS sequencing, it *did not disclose* to a person of ordinary skill in the art random MPS sequencing.