CLEVELAND CLINIC FOUNDATION v. TRUE HEALTH DIAGNOSTICS, LLC, Appeal No. 2016-1766 (Fed. Cir. June 16, 2017). Before Lourie, Reyna, and Wallach. Appealed from N.D. Ohio (Judge Gaughan).

Background:

Cleveland Clinic owns several patents directed to methods for detecting the risk of cardiovascular disease in a patient by detecting myeloperoxidase (MPO) in a bodily sample. True Health, a diagnostic laboratory, purchased the assets of Health Diagnostics Lab, which had contracted with Cleveland Clinic to perform MPO tests. True Health terminated the relationship with Cleveland Clinic and began performing its own MPO tests. Cleveland Clinic sued True Health for infringement of its diagnostic method patents.

True Health filed a motion to dismiss, alleging that the diagnostic method patents were directed to patent-ineligible subject matter. The district court granted True Health's motion to dismiss, finding all claims of the diagnostic method patents ineligible under 35 U.S.C. §101.

Issue/Holding:

Did the district court err in holding that the claims of the diagnostic method patents are directed to ineligible subject matter under §101? No, affirmed.

Discussion:

The Federal Circuit agreed with the district court that the claims of the diagnostic method patents are directed to patent-ineligible subject matter. The Federal Circuit analyzed the claims under the two-step *Alice* framework. Under the first step, the Federal Circuit found that the claims recite a natural correlation between cardiovascular disease and elevated MPO levels. Under the second step, the Federal Circuit held that the claims do not contain an inventive concept sufficient to transform the natural correlation into patent-eligible subject matter.

In its opinion, the Federal Circuit compared the claims to those at issue in *Sequenom*, finding that like the patent-ineligible claims in that case, the present method claims involve detecting a naturally occurring element in a patient sample. The claimed methods then employ the natural correlation between the determined MPO levels and control values to predict a patient's risk of developing or having cardiovascular disease. The Federal Circuit determined that the claimed methods were performed with no meaningful non-routine steps based on the disclosure in the patent specifications that the MPO levels were analyzed by conventional assay techniques, and that those values were compared to control values via known statistical models. Therefore, the Federal Circuit concluded that the claims do not sufficiently transform the natural presence of MPO in a patient sample and its natural correlation to cardiovascular disease into patentable subject matter.