GENETIC TECH. LTD. v. MERIAL L.L.C., Appeal Nos. 2015-1202 and 2015-1203 (Fed. Cir. April 8, 2016). Before Prost, Dyk, and Taranto. Appealed from D. Del. (Judge Stark).

Background:

Genetic Tech sued two defendants alleging that the defendants infringed one of its patents. The patent is directed to a method for detecting at least one coding region allele of a multi-allelic genetic locus. The claim at issue recites a method comprising (1) using a primer to amplify a sequence of non-coding region DNA known to be linked with the coding region allele; and (2) analyzing the non-coding region to detect the coding region allele. The defendants moved to dismiss for failure to state a claim. The district court granted the motion and entered final judgment that the asserted claim of the patent is patent-ineligible under 35 U.S.C. §101. Genetic Tech appealed to the Federal Circuit.

Issue/Holding:

Did the district court err in granting the defendants' motion to dismiss? No, affirmed.

Discussion:

The Federal Circuit held that, under the two-part *Alice* test for patent eligibility, the disputed claim of Genetic Tech's patent (1) is directed to a law of nature; and (2) does not recite any additional elements that are sufficient to provide the inventive concept necessary to render the claim patent-eligible. Under the first part of the test, the court found that claim 1 is directed to a naturally-occurring relationship between non-coding and coding sequences in linkage disequilibrium (i.e., non-coding and coding sequences that tend to be linked together in genomes more often than probability would dictate) and the tendency of such non-coding sequences to be representative of the linked coding sequences. The claim is directed to this discovered linkage between non-coding and coding sequences, but it involves no creation or alteration of DNA, and it does not identify any novel detection techniques. Thus, the court concluded that the claim is directed to a law of nature.

Under the second part of the test, the court considered the two steps implementing the law of nature, "amplifying genomic DNA with a primer" and "analyzing the amplified DNA sequence to detect the allele." Both the amplifying step and the analyzing step were well known at the time of the application. The patent characterizes the amplification step as prior art, and Genetic Tech had expressly argued that the amplification step was a known technique to overcome an enablement rejection during prosecution. Genetic Tech conceded that the techniques to analyze the amplified DNA were known, and the background section of the patent characterizes the two-step combination of amplification and subsequent analysis as prior art.

Genetic Tech argued that no one had previously analyzed man-made (amplified) non-coding DNA to detect a coding region allele, and that this feature of the claim provided a sufficient inventive concept to pass the second step of the *Alice* test. The court disagreed, characterizing the term "to detect the allele" as a mental process step that merely sets forth a routine comparison that can be performed by the human mind. The court noted that the phrase "to detect the allele" simply asks a user to compare the amplified non-coding sequence with a library of non-coding sequences known to be linked to certain coding region alleles. The court concluded that the novelty of this comparison lies in the novelty of the newly discovered natural law and thus does not supply a sufficient inventive concept to make the claim patent-eligible.