

ROCHE MOLECULAR SYS., INC. v. CEPHEID, Appeal No. 2017-1690 (Fed. Cir. October 9, 2018). Before O'Malley, Reyna, and Hughes. Appealed from N.D. Ca. (Magistrate Judge Laporte).

Background:

Roche sued Cepheid for infringement of Roche's patent, which included diagnostic method claims and primer claims.

The diagnostic method claims were directed to a method for detecting *Mycobacterium tuberculosis* (MTB) in a biological sample. The method included (i) subjecting DNA from the sample to polymerase chain reaction (PCR) using primers with specific DNA sequences that target MTB signature sequences, and (ii) detecting the presence or absence of an amplification product indicative of the presence of MTB in the sample.

The representative primer claim was directed to a primer comprising a specific DNA sequence that targets an MTB signature sequence.

Cepheid moved for summary judgment of invalidity under §101, and the district court granted the motion.

Issue/Holding:

Did the district court err in granting summary judgment of invalidity? No, affirmed.

Discussion:

The Federal Circuit held that the diagnostic method claims were directed to a relationship between the naturally occurring signature sequences and the presence of MTB in a sample. It characterized the relationship as "a phenomenon that exists in nature." The court further held that the claims do not contain an inventive concept that transforms the recited judicial exception into a patent-eligible application. The detecting step was a mere "mental determination," and the recited PCR amplification step was routine and conventional. The court concluded that "[e]very time an investigator practices Roche's claimed invention . . . she is simply rediscovering a preexisting natural phenomenon."

In addressing the primer claims, the court relied heavily on its 2014 *BRCA1* decision. In that decision, the Federal Circuit held that "primers . . . are patent ineligible." The *Roche* court therefore dismissed all of Roche's arguments that the claimed primers were chemically and structurally distinct from any nucleic acid that occurs in nature, or from any nucleic acid that can be isolated from naturally occurring DNA; it concluded that "*BRCA1* forecloses Roche's arguments."

In a concurring opinion, Judge O'Malley invited the court to revisit the *BRCA1* decision en banc. She contended that the holding in *BRCA1* was unduly broad because the court ruled on the final question of invalidity instead of only deciding whether the district court abused its discretion in denying a preliminary judgment on the basis that the accused infringer had raised a substantial question of invalidity. The evidentiary record was therefore incomplete in *BRCA1*, and here Roche's experts presented evidence that raised genuine issues of material fact as to whether anything in nature both has the structure and performs the function of the claimed primers.