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Federal Circuit Concurring Opinion Recommends En Banc Review of Prior Ineligible Subject Matter Decision

Article By:

Robert S. Mallin

Jason Seung-Hyun Jang

On October 9, 2018, the United States Court of Appeals for the Federal Circuit affirmed a grant of summary judgment of invalidity due to patent-ineligible subject matter in *Roche Molecular Systems, Inc. v. Cepheid*, No. 2017-1690, applying its prior holding concerning claims directed to similar technology in In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation, 774 F.3d 755, 760 (Fed. Cir. 2014). In a concurring opinion, Judge O'Malley recommended that the full court revisit the holding in *BRCA1*. If the full court decides to revisit *BRCA1*, this could strengthen patent protection for other biotech inventions.

Background

Roche's U.S. Pat. No. 5,643,723 includes claims directed to a method for detecting a pathogenic bacterium using a short, single-stranded nucleotide sequence known as a "primer" and other claims directed to the primers themselves.

Roche accused Cepheid of infringing the '723 patent and Cepheid filed a motion for summary judgment of invalidity under 35 U.S.C. § 101. The U.S. District Court for the Northern District of California granted the motion, relying on the Federal Circuit's holding in *BRCA1* relating to primers. Specifically, the district court held that the claims were unpatentable under § 101 because "the primer claims in this case, which have genetic sequences identical to those found in nature, are indistinguishable from those held to be directed to nonpatentable subject matter in *In Re BRCA1*."

Majority Opinion

The Federal Circuit affirmed the summary judgment of patent ineligibility based on its prior holding in *BRCA1.* Specifically, the majority noted that the primers of the '723 patent have identical nucleotide sequences as naturally occurring DNA, just like the primers in *BRCA1*. The majority rejected Roche's argument that its synthetic primers differed from those in the naturally-occurring gene based on the presence of a 3-prime end and 3-prime hydroxyl group, noting that the "same argument was made in *BRCA1*."

Concurring Opinion

Although Judge O'Malley agreed with the majority that *BRCA1* compelled the conclusion that the claims of the '723 patent are not patent-eligible subject matter, she wrote separately to express her further view that the Federal Circuit should revisit en banc the holding in *BRCA1* at least with respect to Roche's primer claims. *BRCA1* involved an appeal from the denial of a preliminary injunction motion brought early in that case. Judge O'Malley noted that the record in *BRCA1* was underdeveloped and the Federal Circuit in *BRCA1* did not have the benefit of certain arguments and evidence, such as those presented by Roche, which could support a finding that the primer claims are patent eligible. For example, Roche demonstrated the ways in which the claimed primers may differ structurally from anything that occurs in nature.

Judge O'Malley also distinguished the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013). In particular, unlike the claims in *Myriad*, which were neither "expressed in terms of chemical composition, nor" reliant "in any way on the chemical changes that result from the isolation of a particular section of DNA," the primer claims in the '723 patent are expressed in terms of chemical composition and are reliant on the presence of a 3-prime end and a 3-prime hydroxyl group at a nonnaturally occurring location.

Takeaway

Some of the alleged modifications that Judge O'Malley suggests might render Roche's primers patent eligible and could save other patent claims directed to synthetic DNA. If the full court agrees with Judge O'Malley's suggestion to revisit *BRCA1*, this may strengthen patent protection for other biotech inventions.

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