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Intellectual Property Alert: Can §101 be Overcome for Diagnostic Patent Claims?

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Roche Molecular Systems, Inc. v. Cepheid, No. 2017-1690 (Fed. Cir. Oct. 9, 2018) (*Roche*), marks yet another decision from the Federal Circuit affirming invalidity under 35 U.S.C. §101 of diagnostic claims. Roche's U.S. Patent No. 5,643,723 (the '723 patent) recites method of detecting *Mycobacterium tuberculosis* bacterium (MTB) claims through the identification of certain nucleotides. Although "[t]here [was] no doubt that Roche's discovery of these [claimed] signature nucleotides on the MTB rpoB gene [were] valuable contributions to science and medicine, allowing for faster detection of MTB in a biological sample," the Court held that these specific nucleotides were found in nature and were accordingly patent ineligible under §101.

MTB causes tuberculosis and, according to the '723 patent, isolation and identification of MTB typically takes 3-8 weeks. The '723 patent provided a "rapid test that [would] confirm a TB diagnosis and indicate whether it is a drug-resistant strain." Thus the '723 patent was a technical solution (identifying specific nucleotide markers) to a known technical problem (determining whether MTB from a patient was resistant to antibiotics).

The '723 patent has primer and method of detecting MTB claims comprising 1) polymerase chain reaction (PCR) amplification of DNA and 2) determining the presence or absence of any of one of 11 position-specific nucleotides. With respect to the method of detecting claims, the Court affirmed the district court's holding the claims invalid because it was "undisputed that . . . PCR had become a well-understood, routine and conventional technique" and the specific claimed nucleotide sequences were "indistinguishable from their corresponding naturally occurring segments on DNA". With respect to the primer claims, citing *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*[1] (*BRCA1*), the Court held that the primer claims were non-patentable subject matter as they had genetic sequences identical to those found in nature. Although Roche argued that the claimed primers were patent-eligible because its primers had a 3-prime end and a 3-prime hydroxyl group, which were not present in naturally-occurring DNA, the majority disagreed as this same

argument had already been raised in *BRCA1*.

In a concurrence, however, Judge O'Malley suggested that the Court may want to revisit its holding *en banc* in *BRCA1* with respect to the primer claims as its holding was based on an "underdeveloped record" in *BRCA1*. Specifically, Judge O'Malley cited additional facts in *Roche* that were not developed in *BRCA1*:

- Claimed primers are single-stranded while naturally occurring primers are not;
- Claimed primers are comprised of DNA while naturally occurring primers are comprised of RNA;
- Claimed primers are at least 14 nucleotides while naturally occurring primers are only 3-10 nucleotides long; and
- Claimed primers have 3-prime end with 3-prime hydroxyl group while naturally occurring primers lacked 3-prime end with 3-prime hydroxyl group.

Practice Note

The '723 patent was a technical solution to a technical problem; however, it was still found patent-ineligible. To avoid a similar fate, one might incorporate the diagnostic method in a method of treatment claim,[2] or draft claims not taught by the prior art or otherwise claims that the prior art teaches away from.[3] Assuming that a patent specification has not been published, one might alternatively keep the 11 claimed nucleotides and its relationship to MTB a trade secret.[4]

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[1] 774 F.3d 755 (Fed. Cir. 2014).

[2] *See e.g. Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 887 F.3d 1117 (Fed. Cir. 2018) (method of treating claims comprising obtaining biological sample from patient, performing genotyping assay and administering iloperidone at a certain dose depending on whether patient did or did not have CYP2D6 poor metabolizer genotype).

[3] *See Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*,827 F.3d 1042 (Fed. Cir. 2016) (although individual steps were known in art, claims found patent-eligible as prior art taught away from combination of steps).

[4] *See e.g.* Myriad's Trade Secret Trump Card: The Myriad Database Of Genetic Variants (July 18, 2013) available at https://www.pharmapatentsblog.com/2013/07/18/the-myriad-database-of-genetic-variants/ (Myriad stating that its "database allow[ed] Myriad to report definitive findings to over 97% of its patients [while its competitor could] do this only 70-75% of the time").