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Patent Appeal Board Reverses Rejection Of Prostate Cancer Screening Enablement

A patent examiner who rejected an application for a prostate cancer risk screening method based on post-filing data indicating the method did not work in all populations did not provide a reasonable basis to question the enablement that was provided for the claimed invention, the patents appeal board held March 27 (*In re Xu*, B.P.A.I., No. 2009-0938, 3/27/09).

The U.S. Patent and Trademark office's position on such rejections has generated some controversy. An example in an instructional presentation on personalized medicine at the December 2008 meeting of the PTO's Biotechnology/Chemical/Pharmaceutical (BCP) Customer Partnership showing an enablement rejection based on post-filing data suggesting that the claimed method did not work for African-Americans drew criticism during and after the session, both for the nature of the rejection and the reference to race. The slides mentioning race and ethnicity later were replaced on the meeting Web site with ones referencing "population groups" (3 LSLR 96, 1/30/09).

In a "real-life" example of the policy, patent assignee Wake Forest University appealed an examiner's rejection of U.S. Patent Application 10/426.262 to the U.S. Board of Patent Appeals and Interferences. The claims in the application describe a method of screening a subject for increased risk of prostate cancer through the detection of the presence or absence of an MSRI mutation. The mutation is selected from the group consisting of the R293X and the D174Y mutations.

The examiner concluded that post-filing published references suggested that the correlation between the claimed mutations and the risk both of sporadic and hereditary prostate cancers may not be statistically significant in all populations. "Without such a correlation," the examiner wrote, "one skilled in the art would not be able to screen a subject for the risk of prostate cancer."

The examiner specifically noted that the specification disclosed that the hereditary R293X mutation was found in Caucasians, the hereditary D174Y mutation in African Americans, and the same racial pattern pertained for the sporadic R293X and D174Y mutations.

'Reasonably Indicative' Sufficient. In its analysis, the BPAI wrote that the specification provides evidence that the R293X and D174Y mutations occurred in several families with familial or hereditary prostate cancer. While the mutation was not always associated with prostate cancer, 100 percent correspondence was not necessary to meet the limitation of claim 1 of "increased risk of prostate cancer," the board wrote, interpreting "increased risk" to mean an increased possibility or probability of getting prostate cancer when the mutation is present

According to the board, that limitation was met by the disclosure that the R293X and D174Y mutations segregate "well" but not "completely" with prostate cancer in the identified families.

Addressing the examiner's concerns about the correlation of the mutations and race, the BPAI wrote, "While it may be true that the Specifications teachings indicated that the elevated cancer risk for the R293X and D174Y mutations might be correlated with a subject's race, there is still sufficient evidence that the generic claim for detecting increased prostate cancer risk is enabled by the Specification. It is not a function of the claims to specifically exclude possible inoperative embodiments." The board found support for its statements in *In re Angstadt*, 537 F.2d 498 (CCPA, 1976) and *Atlas Powder Company v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984).

The board noted that the examiner also stated the specification did not enable the claimed method because there was no "significant correlation" between prostate cancer risk and the R293X and D174Y mutations. The examiner's conclusions were based on post-filing publications that determined the incidence of R293X and D174Y mutations were not associated with cancer risk.

"It is unnecessary for Appellants to prove with 100% certainty that a correlation exists between the R293X and D174Y mutations and an increased prostate cancer risk. It is sufficient that the evidence is 'reasonably indicative' that a correlation is present," the board wrote. It added that there is no reason to treat a gene mutation whose activity is to elevate prostate cancer risk differently from a compound having a pharmacological activity.

Accordingly, the BPAI reversed the rejection of claims 1 and 5-8 of the '262 application.

Attorney's Comment. The case was heard before administrative patent judges Donald E. Adams, Eric Grimes, and Richard M. Lebovitz. The appeal was filed by Sherry I. Murphy, of Myers Bigel Sibley & Sajovec, Raleigh, N.C.

Murphy told BNA, "As a patent attorney using established law to counsel clients, it is encouraging to find that classic cases like *In re Angstadt* and *Atlas Powder* are thoughtfully applied by the board to new technology. The decision also just makes sense. Post-filing data indicating that a specific sub-population of patients may not show a correlation should not render a claim non-enabled. Otherwise, a party trying to invalidate a claim

in litigation may be encouraged to go on a 'fishing expedition' by testing patient cohorts in search of one for which the claimed association or pharmacological effect is not found."

Murphy also said that as to diagnostics, "one of skill in this art is clearly capable of affording the proper weight to a genetic risk factor in the context of the overall patient profile in determining the increased disease risk."

BY JOHN T. AQUINO

The decision can be found at <http://op.bna.com/hl.nsf/0?Open=jako-7rlmq3>.