Update: Myriad Genetics Patent Case

By Kim Baker, M.S., R.N., CRAAB! Member

In the Winter/Spring 2010 newsletter, I reported on a lawsuit that was filed by The American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT) on behalf of various medical groups, patients and researchers against Myriad Genetics. Myriad Genetics isolated, owns and patented the two breast and ovarian cancer genes BRCA1 and BRCA2. Additionally, Myriad Genetics developed an expensive test to identify the mutation found in these genes that indicates whether a woman is at a high risk of getting breast or ovarian cancer.

The plaintiffs argue that the current patent on the genes prevents other laboratories from developing both similar less costly tests that further validate results as well as potential therapies. Those in the scientific community fear that lack

of patentability could undermine incentives to develop these expensive personalized tests. This case, closely watched because it calls into question the patents held on approximately 2,000 human genes, could have a far reaching effect on medical research.

When last reported, federal court Judge Robert Sweet of NY had delivered a precedent-setting ruling that patents on genes associated with hereditary breast and ovarian cancer were invalid. The judge wrote that the patents on the breast cancer genes were improperly granted because human genes are indeed products of nature and that nature cannot be patented. This judgment was later reversed by the Court of Appeals for the Federal Circuit specializing in patent cases, which in a 2-to-1 decision said that DNA isolated from the body *could* be patented because it was "markedly different" in chemical structure from the DNA inside the body.

The plaintiffs then appealed to the Supreme Court which decided in March of 2012, that it will not be hearing the case, instead sending it back to the appellate court, asking that they reconsider. The Federal Circuit Court of Appeals will then issue a decision with the same or a different outcome. CRAAB! will continue following this important case.

You can learn more at www.aclu.org/brca