Position of Genetic Alliance on Breast Cancer Gene Patent Case

WASHINGTON – January 29, 2010 – Genetic Alliance, a nonprofit health advocacy organization, looks forward to the court’s consideration of summary judgment motions in the gene patent case of Association for Molecular Pathology et al v. US Patent and Trademark Office et al, which will take place on February 2, 2010, in the federal District Court in the Southern District of New York. The organization issued the following comment:

Individuals and families need breakthrough treatments for genetic diseases, and therefore Genetic Alliance recently filed an *amicus curiae* (friend-of-the-court) brief in this case opposing the plaintiffs’ positions. We filed the brief not only because we disagree with the plaintiffs’ factual and legal positions but, more importantly, because the plaintiffs are making demands that would, if adopted by the court, undermine genetic and biotechnology advances urgently needed by patients.

This case involves more than patents on specific breast cancer gene sequences. In fact, plaintiffs are calling for the wholesale abolition of all gene patents. This attack is so broad that if the courts were to uphold it, tens of thousands of patents on not only gene sequences but also biologic drugs, vaccines, and tests would be threatened. The legal mess resulting from weakening or abolishing patent protections would be enormously disruptive to the complex process of translating basic science discoveries to clinical applications. Patent protections for biomedical innovations are essential to attract the enormously risky investments needed to create diagnostic tests and treatments.

Gene patents are legal today under federal law that has been repeatedly affirmed by the courts. In fact, “gene patents” are not on the genes themselves. Rather, what we call gene patents refers to patents on isolated and purified DNA molecules, which are man-made chemical compounds capable of uses that genes in their natural state are not.

“We entered this case to give voice to the individuals and families who desperately need medical innovations,” said Sharon Terry, President and CEO of Genetic Alliance. Ms. Terry has two children diagnosed with PXE, a rare genetic disorder that threatens blindness, cardiovascular disease, and other problems. Upon receiving her children’s diagnosis, she collaborated with scientists in the search for the PXE gene and is a co-inventor of the patent...
on the gene sequence. She has given her rights to the patent to the nonprofit foundation PXE International. “We view PXE International as a steward of the gene. As a result of holding the patent, we are able to license it to a genetic testing lab for a token fee to ensure broad accessibility and high quality testing,” said Ms. Terry. “It’s wonderful that we have a genetic test for PXE now, but I want to emphasize that we do not have any treatments. The clock is ticking, not just for my children, but for millions of people, affected by thousands of diseases, who need treatments that do not exist today.”

Genetic Alliance wants our nation’s laws to strike the difficult balance of encouraging innovation and ensuring quality and accessibility for tests and treatments. Incentives – social, financial, and legal – are crucial to protect and advance medical discoveries all the way through the development cycle – from basic research through commercialization of products. This cycle must be accelerated, and we therefore oppose the broad abolition of all gene patents sought by the plaintiffs in this case.

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About Genetic Alliance
Genetic Alliance transforms health through genetics, promoting an environment of openness centered on the health of individuals, families, and communities. Genetic Alliance brings together diverse stakeholders that create novel partnerships in advocacy; integrates individual, family, and community perspectives to improve health systems; and revolutionizes access to information to enable translation of research into services and individualized decision making. For more information about Genetic Alliance, visit [http://www.geneticalliance.org](http://www.geneticalliance.org).

About PXE International
PXE International initiates, funds, and conducts research, provides support for individuals and families affected by pseudoxanthoma elasticum, and provides resources for healthcare professionals. PXE International is the assignee and licensing agent for the PXE gene patent. Sharon Terry, the executive director of PXE International, is a co-inventor of the PXE gene patent but receives no income from the patent. The patent is licensed to test providers for a token fee in order to ensure wide availability of PXE tests from a quality provider, and the testing results are added to an open access mutation database hosted by the National Institutes of Health in order to accelerate progress toward a treatment. For more information about PXE International, visit [http://www.pxe.org](http://www.pxe.org).