Remarks of Dr. Triantafyllos Tafas

NJIPLA Jefferson Medal Award Dinner

June 4, 2010

Mr. President and Members of the New Jersey Intellectual Property Association, Jefferson Medalists, Ladies and Gentlemen--Good Evening.

I am deeply honored to be recognized by this wonderful organization.

The *Tafas v. Dudas/Doll/Kappos* case is now over, all issues are now finally resolved. And at the same time, I am happy to report that the permanent injunction by the District Court of Virginia remains in force, prohibiting the institution of the same or similar rules in the future. It is useful to remember that one of the main reasons for that rulemaking, was to address the significant backlog of patent applications; then the perceived approach was to restrict the ability to file new applications. Today, the USPTO, is following another path, fully aligned with the current needs of the American Economy, one that facilitates processing of patent applications and releases intellectual property to foster much needed growth.

I am sure many of you are curious about what compelled me to bring suit against the USPTO concerning its new claims and continuation rules, which, at that time, the vast majority in the patent field felt were a done deal. Of course, other companies, larger than my fledgling companies, were certainly going to be hurt much more by the new regulations. For example, consider the effect of such rules upon biotechnology companies, pharmaceutical and chemical companies, emerging companies of all types and venture capital companies, all of which depend heavily on continuation applications and RCE's.

My story begins in Greece, where as a faculty member in the University of Athens, I had an idea about creating a system that would make disease diagnosis more sensitive. A method to detect very rare cells in the human body, found in places where they would not, normally, appear. The initial idea was to use such a system for the detection of fetal cells in maternal blood, during pregnancy, and use these cells for non-invasive, prenatal diagnosis of Down syndrome. Soon it became apparent that such a method would bring great benefit for cancer diagnoses and bring new opportunities for the treatment of millions of people who suffer from the disease. As have others in the medical community, I recognized that drugs and treatments we use today are, oftentimes, ineffective to cause a cure. Personal experience with members of my own family brought home this problem. Great strides are being made in medicine, but many of the common

cancers are not curable simply because they have progressed too far before they are discovered. A new, more sensitive method allowing earlier diagnosis by detecting cancer cells before they reached a stage wherein cure was no longer feasible, would be beneficial.

It was known for decades that, cancer cells, escape in the blood at an early stage of the disease; unfortunately though, at that stage they can be as rare as 1 in 100 million or 1 in a billion of blood cells. Providing such clinical diagnosis, by conventional microscopy, is impossible. I felt what was truly needed was an automated microscopy system that could read microscopic preparations, driven by artificial intelligence to report potential cancers without the intensive involvement of clinicians as was the case with conventional testing.

My dream was met with much skepticism in Greece. Although I searched for investors, no one wanted to invest money into such a project, which many pointed out, much larger companies had unsuccessfully undertaken. Many Greek investors were all too glad to point out that, what I was proposing would entail the combined efforts of numerous electrical, computer, software, and mechanical engineers, as well as chemists, biochemists and biologists. Even when I turned to European investors outside Greece, I heard the same story.

After many unsuccessful attempts to raise capital in Europe, along with Petros Tsipouras, a colleague of mine, we turned to the United States. Petros, a well-respected geneticist with a successful academic career, was already apprised of the benefits, that the United States patent system can offer to small entities and individual entrepreneurs. He believed U.S. based investors could be attracted so long as we could show that our idea had merit, and equally importantly, show that our ideas/technology were patent protectable.

I found the United States exceptional in that it provided strong patent protection, affordable not only by large corporate entities, but also by small businesses and individuals. Based on our early research and the patent applications filed, my colleagues and I were able to raise the needed seed funding to start our microscopy company – Ikonisys, at the Yale Science Park in New Haven, CT. While we faced many difficulties and struggles in starting our company, and developing a commercial product, after many years I am glad to report that Ikonisys now manufactures and sells a technologically-complex robotic microscope that is used by many research and clinical facilities. I presently serve as Ikonisys' Chief Technology Officer.

Our work in automated microscopy is augmented by the recent advances in genomics and proteomics. We open a new potential for molecular pathology to monitor cancer progression and

efficiency of treatment; as well as, to screening for early stage cancers; and our work continues to this day. We were fortunate to work with some of the most famous cancer researchers in the international scene to make this happen. We introduced a new cell based, molecular test well positioned in the diagnostic pathway of cervical cancer. We are seeing concrete results from testing peripheral blood samples taken during routine physical exams to find circulating cancer cells; a test with an immediate application as a companion diagnostic and a clear potential to be used for screening at the very earliest stages of the disease. I believe that our research and development, does hold revolutionizing potential for early cancer detection and treatment.

In 2006, my patent attorneys at Kelley Drye & Warren, and specifically Dr. Steve Moore Esq., informed me of an article he had written discussing the intentions of the USPTO to implement new rules that substantially limit continuations, Requests for Continuing Examination and the number of claims. I read the article intently as it set forth the possible dire consequences of such regulation on emerging companies and a vast array of biomedical companies. Recognizing that any substantial long-term success in developing and commercializing my technologies in the United States was directly related to my ability to obtain patent protection, I immediately saw the danger to emerging companies like Ikonisys. I truly hoped that such regulations would never come into being. Unfortunately, I was wrong. The USPTO published the Final Rules in the Federal Register on August 21, 2007, with an effective date of November 1, 2007. On August 22, 2007 we filed a complaint in the United States District Court for the Eastern District of Virginia seeking to invalidate and enjoin the Final Rules. Again, I brought the case against the USPTO because I believed the rules would hurt innovation generally and restrict the ability of pharmaceutical and biotechnology companies to develop innovative life saving technologies in the future.

I fully expected other larger industry players would quickly follow our lead, and two months later, on October 9, 2007, GlaxoSmithKline filed, what would later be characterized by Judge Cacheris and the DOJ, a similar complaint to my own and within a few weeks consolidated.

In my view, the consolidated case made for a great united front, with one of the largest pharmaceutical companies and a individual inventor/entrepreneur effectively joining forces to make common cause against the proposed rules.

As a result of our combined efforts, the District Court entered judgment in our favor

enjoining the Rules. The USPTO appealed this ruling to the U.S. Court of Appeals for the Federal Circuit. While I was very pleased that the panel struck down the continuation regulations, I sought rehearing *en banc* on those regulations involving RCEs and claim limitations, which were not struck down. After the grant, by the Federal Circuit panel, of the separate motions for rehearing *en banc* filed by me and GSK, and after the Federal Circuit vacated the panel decision shortly thereafter. The USPTO announced withdrawal of the Final Rules in 2009 with the change in administration. On that ground, in October 2009, the USPTO moved the Federal Circuit for dismissal of the pending appeal, as well as for an order vacating the district court judgment entered in our favor. While agreeing that the withdrawal of the regulations necessitated the dismissal of the pending appeal as moot, I also believed that the District Court's judgment and permanent injunction should remain in place and therefore, I opposed the motion seeking *vacatur*. The Federal Circuit agreed and on November 13, 2009, issued an Order dismissing the pending appeal as moot but denying the motion seeking vacation of the district court judgment in our favor. As a result, the permanent injunction against promulgation of similar continuation rules in the future remains an integral part of our jurisprudence.

Today's state of the United States economy, requires that the seeding power of individual inventors and entrepreneurs, not only is kept intact but further fostered. Growth is dependent on the ability of small enterprises to raise capital and create the new, promising technologies and products. From fiber optics to pharmaceuticals, computers to biotechnology, from nanotechnology to green technology, high value products can be developed and thus, create a huge number of highly paying jobs. It is an established fact that small businesses create 2 out of 3 jobs in America. This is the way to keep in our economy, the intellectual capital produced in our Academic institutions and continue attracting talent from all over the world.
Small companies are primarily the great innovators; again and again in the history of the American economy small emerging companies were the basis for re-ignition of growth. Innovation combined with sound business practices, is the path to success. Investment of capital leads to real, sustainable growth.

More so than in previous times however, protection of innovation is important. In the internet connected global markets, a new product or technology, can be easily copied in other parts of the world. The patent system and the USPTO are the protective barriers against that

happening. In the last period of time and as late as two days ago, Mr. David Kappos, Undersecretary of Commerce for Intellectual Property and Director of the USPTO, repeated that "the US Economic Security depends on the National Intellectual Property Strategy". A new set of rules was just announced, introducing a "Three Track" program for patent application examination; this has a real potential to efficiently deal with the huge backlog of patent applications and, therefore, release a significant amount of intellectual property. I am convinced that this market driven approach in managing intellectual property will give a real boost for value creation by small and large companies alike.

I want once again to express my gratitude for the honor to bestow to me this exceptional award. The mere fact that I am here today, driving, along with an exceptional team of partners and staff the growth of a highly promising biotechnology company; having had the humbling opportunity to contribute in the betterment of the intellectual property system; and that, having started as Faculty member in the University of Athens, is a proof of the American uniqueness. We all are offered the opportunity to sustain and protect it.

Thank you