



THE AIDS INSTITUTE

**PUBLIC COMMENT FROM THE AIDS INSTITUTE
TO THE
INTELLECTUAL PROPERTY ENFORCEMENT COORDINATOR
REGARDING
THE JOINT STRATEGIC PLAN**

The AIDS Institute (TAI) began as a grass roots community advocacy effort in the late 1980s. In 1992, this advocacy network became incorporated as Florida AIDS Action, a nonprofit organization. Over the past several years, TAI expanded its vision to become a leading national public policy research, advocacy, and education agency with offices in Tampa, and Washington, DC. Affiliated with the Division of Infectious Diseases and Tropical Medicine at the University Of South Florida College Of Medicine, The AIDS Institute remains focused on HIV/AIDS while incorporating work on related healthcare issues such as Hepatitis, as well as other infectious and chronic diseases. As an advocacy organization for people living with and affected by HIV/AIDS specifically, and as an advocate for patients living with and suffering from any disease or illness generally, The AIDS Institute submits these comments in support of intellectual property rights and rigorous enforcement of regulations against intellectual property infringement.

The AIDS Institute believes that the medicines that patients are using today – brand name or generic – are available because of policies and laws that encourage innovation. Strong patent protections and other incentives encourage pharmaceutical research, development and innovation. Since 1987, approximately 32 drugs have been developed to treat HIV/AIDS. These innovations have turned what was once a terminal illness into a potentially chronic, manageable condition. Technology, research, and innovation have expanded the horizon of possibilities for saving lives. HIV/AIDS care and treatment has been transformed. Strong patent laws created an environment for investment that has led to the discovery of life-saving antiretroviral drugs; led to increase adherence to treatment by lowering the pill burden – regimens have gone from upwards of 20 pills a day to just one a day; and increased life expectancy of people living with HIV/AIDS. All of these life-saving drugs were developed, in large part, with private investment and it is our opinion that this was only possible because pharmaceutical and biotechnology companies were able recoup their investment in the extensive clinical research and clinical trials required to make these drugs available to the people that need them. It is our belief that strong patent rules and other incentives that encourage pharmaceutical research, development and innovation offer the best hope to patients with life-threatening diseases for which there are few or no treatment options. Pharmaceutical research would not be economically feasible without intellectual property protection.

The AIDS Institute's affiliation with the University of South Florida (USF), has allowed us to see how patent laws provide a powerful incentive for exploration and discovery. Investment in research and development entails significant risk that must be balanced by potential rewards. In 1980, Congress allowed universities for the first time to obtain patents for innovations resulting from their federally funded research. The University of South Florida (USF) is one of the nation's top

63 public research universities and one of 76 community-engaged, four-year universities as designated by the Carnegie Foundation for the Advancement of Teaching. Since 2003, USF has been issued approximately 191 patents. USF faculty members are regularly granted 30 to 40 patents a year for new inventions. These patents generate substantial revenue for the university. Currently, TC-5214, a depression drug created and patented by a team of University of South Florida researchers, is at the center of a major deal between global pharmaceutical company AstraZeneca PLC and Targacept, Inc., earning the university potentially its most lucrative patent royalties to date (www.physorg.com). TC-5214 is viewed as a promising alternative to antidepressants currently on the market and with fewer side effects. This is an extraordinary development for the nearly 42 million people worldwide who are affected by major depressive disorders. Discoveries such as this not only create huge economic benefits for public and private universities, but also far-reaching health care and other benefits for millions of Americans.

The AIDS Institute believes that research and development is directly linked to the protection of intellectual property. We believe that weakening patent rules or failing to protect intellectual property does little to expand drug coverage for patients who lack access to medicines. In fact, evidence from a recent report from the Organization for Economic Cooperation and Development (OECD), suggests that weak patent rules often contribute to the entry of counterfeit or substandard drugs into the supply chain in many countries. Intellectual property protection has an important impact on drug safety and global health. Patented medicines, having withstood the rigors of testing, come with a guarantee of quality and integrity. Counterfeit drugs are not only unsafe, but also contribute to the rise in resistance to the treatments and the rise of resistant strains of viruses and bacteria.

The AIDS Institute believes that intellectual property protection is critical to finding solutions to current challenges to world health. As a society, we are eager in anticipation of the cure for cancer, HIV/AIDS, diabetes, and neurological disorders such as Alzheimer's or Parkinson's disease. Without intellectual property protection we would not have iPods, cell phones, new drugs and diagnostics, or any number of innovations readily available to society today. We hope that the Joint Strategic Plan being developed by the Office of Management and Budget maintains strong provisions for intellectual property protection.

Respectfully submitted,



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