

Knowledge (“I-MAK”), Knowledge Ecology International (“KEI”), Prescription Access Litigation (“PAL”), Public Knowledge (“PK”), Research on Innovation (“ROI”), and Software Freedom Law Center (“SFLC”) (collectively “Public Interest Amici”), by undersigned counsel, move for leave to file a brief as *amici curiae* in support of defendants Jon W. Dudas' and United States Patent and Trademark Office's (collectively “USPTO”) anticipated motions for summary judgment.

The Public Patent Foundation (“PUBPAT”) is a not-for-profit legal services organization that represents the public interest in the patent system, and most particularly the public interest against the harms caused by undeserved patents and unsound patent policy. PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the system governing patents with representation, advocacy and education. PUBPAT has argued for sound patent policy before the Supreme Court, the Court of Appeals for the Federal Circuit, the USPTO, the European Union Parliament, and the United States House of Representatives. PUBPAT has also requested that the USPTO reexamine specifically identified undeserved patents causing significant harm to the public. The USPTO has granted each such request. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

The Computer & Communications Industry Association (“CCIA”) is a not-for-profit trade association dedicated to principles of full, fair, and open competition. CCIA members participate in many sectors of the computer, information technology, and telecommunications industries and range in size from small entrepreneurial firms to the largest in the industry. CCIA members use the patent system regularly, and depend upon it to fulfill its constitutional purpose of promoting

innovation. However, CCIA is increasingly concerned that the patent system has expanded without adequate accountability and oversight.

AARP is a nonpartisan, nonprofit membership organization of over 39 million persons, age 50 or older, dedicated to addressing the needs and interests of older Americans. As the country's largest membership organization, AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. AARP, therefore, has a strong interest in this case since pharmaceutical companies' manipulation of the patent system has thwarted the entry of generics to the marketplace, thereby reducing access to affordable prescription drug treatments. Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar expended on prescription drugs.¹ Prescription drug spending has skyrocketed over the last decade and a half. Since 1990, national health expenditures on prescription drugs have quadrupled from \$40 billion to \$188 billion in 2004. Because prescription drug spending has skyrocketed over the last fifteen years, thereby limiting AARP's members' access to medically necessary medicines,² AARP advocates for policies that can broaden access to prescription drugs, such as adding prescription drug coverage to the Medicare program (Part D), and for policies that lower the cost of prescriptions for consumers. Since generic drugs generally cost much less than

1 Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010* at 2 (July 2000).

2 See e.g. AARP, *Rx Watchdog Report*, June 2007, Vol. 4, Issue 5, available at http://www.aarp.org/issues/rx_watchdog/a2004-10-25-watchdog-archive.html.

their brand-name counterparts, AARP has worked at the state and national levels to increase access to lower cost generic versions of drugs.

The Consumer Federation of America (“CFA”) is the nation's largest consumer-advocacy group, composed of over 280 state and local affiliates representing consumer, senior citizen, low income, labor, farm, public power and cooperative organizations, with more than 50 million individual members. CFA represents consumer interests before federal and state regulatory and legislative agencies and in court proceedings.

Essential Action is a project of Essential Information, a non-profit, tax-exempt organization founded in 1982 that encourages citizens to become active and engaged in their communities. Essential Action is concerned particularly about the harmful impact of poor quality patents on prescription drug prices and medicine affordability, and more generally about the negative impact the patent system can have on the public when it is abused by patent applicants.

The Foundation for Taxpayer and Consumer Rights (“FTCR”) is a nationally recognized non-partisan, non-profit organization representing the interests of taxpayers and consumers. Its mission is to provide an effective voice for taxpayers and consumers in an era when special interests dominate public discourse, government and politics. FTCR's programs include health care reform, oversight of insurance rates, energy policy, protecting legal rights, corporate reform and political accountability. FTCR's Stem Cell Oversight and Accountability Project seeks to protect the interests of California taxpayers and patients as California's landmark \$6 billion stem cell research project is implemented. As part of its Stem Cell Project, FTCR successfully sought re-examination of three patents on embryonic stem cells that were impeding research efforts.

FTCR continues to oppose unjust patents that hinder research and hurt patients.

The Initiative for Medicines, Access & Knowledge (“I-MAK”) is a not-for-profit group that provides technical assistance on intellectual property and pharmaceutical products to governments, suppliers promoting access, public health organizations and civil society groups. I-MAK challenges unsound patent systems globally and works toward creating systemic change so that newer and more affordable drugs are made available for the public. I-MAK also offers tools and resources to the public helping increase knowledge of the pharmaceutical patenting process.

Knowledge Ecology International (“KEI”) is a not-for-profit organization with offices in Washington, DC, London and Geneva. KEI searches for better outcomes, including new solutions, to the management of knowledge resources, with an emphasis on the needs of consumers and low income persons. KEI's primary focus at present concerns the best way to reconcile innovation and access (i+a) for medical technologies, including pharmaceutical drugs. KEI is also concerned that unwarranted encroachments on the public domain by patents that lack appropriate standards for inventive step will harm efforts to develop open standards for information technologies.

Prescription Access Litigation LLC (“PAL”) is a project of Community Catalyst, Inc., a nonprofit, nonpartisan organization that builds consumer and community participation in the shaping of the U.S. health system to ensure quality, affordable health care for all. PAL is a coalition of over 130 organizations in 35 states and the District of Columbia. The organizations in PAL's coalition have a combined membership of over 13 million people, and include state and local organizations representing consumers and seniors, statewide health care access coalitions, and labor unions. PAL works to end illegal prescription drug price inflation by pharmaceutical

manufacturers and others by facilitating the participation of consumers, advocacy organizations and third party payors (health plans, union benefit funds and others) in class action litigation challenging such price inflation practices. PAL joins this brief because PAL is concerned that abuse of the patent system leads to higher prescription drug prices for consumers.

Public Knowledge (“PK”) is a public interest advocacy and education organization that promotes a balanced approach to intellectual property law and technology policy reflecting the “cultural bargain” intended by the framers of the U.S. Constitution. PK promotes fundamental democratic principles and cultural values of openness, access, and the capacity to create and compete. PK advocates for patent law and policy that encourages innovation and creativity.

Research on Innovation (“ROI”) is a not-for-profit organization created to conduct, sponsor and promote research on technological innovation and to disseminate the results of this research to a broad audience, both in academia and in industry. ROI's research indicates that patents can have a substantial positive impact on innovation if patent policy is sound and balanced.

The Software Freedom Law Center (“SFLC”) is a not-for-profit legal services organization that provides legal representation and other law-related services to protect and advance Free and Open Source Software (FOSS), software distributed under terms that give recipients freedom to copy, modify and redistribute the software. SFLC provides pro bono legal services to non-profit FOSS developers and helps the general public better understand the legal aspects of FOSS. SFLC is concerned about the impact the patent system has on the development and distribution of FOSS.

The Public Interest Amici wish to submit a brief addressing the public interest impact of the USPTO's final rules published on August 21, 2007, *Changes to Practice for Continued*

Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) (“Final Rules”). More specifically, the Public Interest Amici will address how the public interest will be well served by the Final Rules because they will help the USPTO curtail abusive behavior by exploitative patent applicants and improve patent quality. The Public Interest Amici will also address how the Final Rules, because of their positive impact on the public interest, are fair, rational and reasonable. Finally, the Public Interest Amici will address why equity also supports the Final Rules.

As discussed more fully in the accompanying memorandum, the Public Interest Amici, despite having various missions and activities, are united in their belief that patent law and policy should be crafted to ensure that it benefits the public interest, and not just the special interests of patent holders and patent attorneys. More specifically to this case, the Public Interest Amici firmly believe that the Final Rules would significantly advance both the general public interest and the specific aspects of the public interest that they each separately exist to represent. Thus, the Public Interest Amici are united in their wish to express a single voice in support of the Final Rules.

The Public Interest Amici have no financial interest in any of the parties in this case and seek leave to participate as *amici* based upon their mutually shared interest in ensuring that patent law and policy reflect the interests of all Americans, and not just the special interests of patent holder and patent attorneys.

The Public Interest Amici submit this motion, its supporting memorandum, and the accompanying brief according to the Court's November 29, 2007, Order regarding scheduling of

amici briefs for these cases. Counsel for the Defendants in both C.A. No. 1:07cv846 and C.A. No. 1:07cv1008 have consented to the filing of this brief. Consent of counsel for the Plaintiffs was requested. The GSK Plaintiffs took no position on the request for consent and the Tafas Plaintiff objected to the request for consent. The Public Interest Amici do not request oral argument on their Motion for Leave. A proposed Order is attached.

WHEREFORE, for the reasons stated herein and for good cause shown, the Public Interest Amici respectfully request that the Court grant them leave to file an *amici* brief in support of the defendants' anticipated summary judgment motions.

Respectfully submitted,

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Dated: December 20, 2007

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of December 2007, I caused a copy of the foregoing JOINT MOTION OF *AMICI CURIAE* PUBLIC PATENT FOUNDATION, COMPUTER & COMMUNICATIONS INDUSTRY ASSOCIATION, AARP, CONSUMER FEDERATION OF AMERICA, ESSENTIAL ACTION, FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS, INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE, KNOWLEDGE ECOLOGY INTERNATIONAL, PRESCRIPTION ACCESS LITIGATION, PUBLIC KNOWLEDGE, RESEARCH ON INNOVATION, AND SOFTWARE FREEDOM LAW CENTER FOR LEAVE TO FILE A BRIEF IN SUPPORT OF DEFENDANTS' ANTICIPATED MOTIONS FOR SUMMARY JUDGMENT and accompanying proposed order to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing to the following:

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