

08-1352

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TRIANAFYLLOS TAFAS,

Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as
GlaxoSmithKline), SMITHKLINE BEECHAM PLC, and GLAXO GROUP
LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

v.

JON DUDAS, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR
OF THE UNITED STATES PATENT & TRADEMARK OFFICE, AND UNITED STATES PATENT
AND TRADEMARK OFFICE,

Defendants-Appellants.

On Appeal from the United States District Court for the Eastern District of Virginia in
Consolidated Case Nos. 1:07-CV-846 and 1:07-CV-1008, Senior Judge James C. Cacheris

**MOTION OF *AMICI CURIAE* PUBLIC PATENT FOUNDATION, AARP,
COMPUTER & COMMUNICATIONS INDUSTRY ASSOCIATION,
CONSUMER WATCHDOG, ESSENTIAL ACTION, INITIATIVE FOR
MEDICINES, ACCESS & KNOWLEDGE, PRESCRIPTION ACCESS
LITIGATION, PUBLIC KNOWLEDGE, RESEARCH ON INNOVATION,
AND SOFTWARE FREEDOM LAW CENTER
FOR LEAVE TO FILE BRIEF IN SUPPORT OF APPELLANTS**

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Counsel for *Amici Curiae*

July 29, 2008

CERTIFICATE OF INTEREST

Counsel for *Amici Curiae* certifies the following:

1. The full name of every party or amicus represented by me is: Public Patent Foundation; AARP; Computer & Communications Industry Association; Consumer Watchdog; Essential Action; Initiative for Medicines, Access & Knowledge; Prescription Access Litigation; Public Knowledge; Research on Innovation; and, Software Freedom Law Center.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: Not Applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amici curiae* represented by me are: None.

4. The names of all law firms and the partners or associates that appeared for the party or amici now represented by me in the trial court or agency or are expected to appear in this court are:

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Dated: July 29, 2008

/s/Daniel B. Ravicher/s/
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PUBLIC PATENT FOUNDATION
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The Public Patent Foundation (“PUBPAT”), AARP, Computer & Communications Industry Association (“CCIA”), Consumer Watchdog, Essential Action, Initiative for Medicines, Access & Knowledge (“I-MAK”), Prescription Access Litigation (“PAL”), Public Knowledge (“PK”), Research on Innovation (“ROI”), and Software Freedom Law Center (“SFLC”) (collectively “Public Interest Amici”) hereby move for leave to file a brief as *amici curiae* in support of Appellants.* As described more fully below, the Public Interest Amici represent substantial interests in this case and can present the Court with unique perspectives on some of the relevant issues.

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

* Requisite copies of the proposed brief are enclosed herewith. Defendants-Appellants and Plaintiff-Appellee GlaxoSmithKline gave their consent to the submission of the brief. Plaintiff-Appellee Tafas took no position on the request for consent made of it by the Public Interest Amici.

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, this Court, the United States House of Representatives, the USPTO, and the European Union Parliament. 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.

AARP is a nonpartisan, nonprofit membership organization with nearly 40 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

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.

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

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.

Consumer Watchdog (“Consumer Watchdog”) 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. Consumer Watchdog's programs include health care reform, oversight of insurance rates, energy policy, protecting legal rights, corporate reform and political accountability. Consumer Watchdog'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, Consumer Watchdog successfully sought re-examination of three patents on embryonic stem cells that were impeding research efforts. Consumer Watchdog continues to oppose unjust patents that hinder research and hurt patients.

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 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.

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, 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. As such, the Public Interest Amici wish to submit a unified 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 wish to express a single voice through their brief that addresses how the public interest will be well served by the Final Rules, how the Final Rules, because of their positive impact on the public interest, are fair, rational and reasonable, and why equity also supports the Final Rules.

For the reasons set forth above, the Public Interest Amici respectfully request that the Court grant leave to file the attached *amici curiae* brief in support of Appellants.

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Respectfully submitted,

July 29, 2008

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ORDER

The Motion of Public Patent Foundation, AARP, Computer & Communications Industry Association, Consumer Watchdog, Essential Action, Initiative for Medicines, Access & Knowledge, Prescription Access Litigation, Public Knowledge, Research on Innovation, and Software Freedom Law Center for Leave to File Brief as Amici Curiae is hereby granted.

So Ordered, this ____ day of _____, 2008.

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CERTIFICATE OF SERVICE

I, Daniel B. Ravicher, hereby certify that I caused one original and 14 copies of the foregoing:

Motion of *Amici Curiae* Public Patent Foundation, AARP, Computer & Communications Industry Association, Consumer Watchdog, Essential Action, Initiative for Medicines, Access & Knowledge, Prescription Access Litigation, Public Knowledge, Research on Innovation, and Software Freedom Law Center for Leave to File Brief in Support of Appellants

to be sent by Federal Express for filing on the 29th Day of July, 2008 to:

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I further certify that two copies of the foregoing Motion of *Amici Curiae* were served on the 29th Day of July, 2008, by Federal Express on the following counsel of record:

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