

IN THE UNITED STATES DISTRICT COURT FOR THE  
EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

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TRIANTAFYLLOS TAFAS, )  
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 Plaintiff, )  
 v. ) Case No. 1:07cv846 (JCC/TRJ)  
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 JON W. DUDAS, et al., )  
 )  
 Defendants. )  

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CONSOLIDATED WITH

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SMITHKLINE BEECHAM )  
 CORPORATION, et al. )  
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 Plaintiffs, )  
 v. ) Case No. 1:07cv1008 (JCC/TRJ)  
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 JON W. DUDAS, et al., )  
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 Defendants. )  

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**BRIEF FOR 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 IN SUPPORT OF DEFENDANTS' ANTICIPATED MOTIONS FOR SUMMARY JUDGMENT**

**I. THE PUBLIC INTEREST AMICI**

The Public Patent Foundation (“PUBPAT”), Computer & Communications Industry Association (“CCIA”), AARP, Consumer Federation of America (“CFA”), Essential Action, Foundation for Taxpayer and Consumer Rights (“FTCR”), Initiative for Medicines, Access &

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”) respectfully submit this brief in support of defendants Jon W. Dudas' and United States Patent and Trademark Office's (collectively “USPTO”) anticipated motions for summary judgment.

The Public Interest Amici believe that the public interest overwhelmingly supports 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 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. For these reasons, the Final Rules are unquestionably reasonable and rational. In addition, equity also favors the Final Rules. As such, this Court should grant the USPTO's anticipated motions for summary judgment.

#### **A. Background**

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.<sup>1</sup> 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,<sup>2</sup> 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 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

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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](http://www.aarp.org/issues/rx_watchdog/a2004-10-25-watchdog-archive.html).

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, 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. 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 have united in this brief to express a single voice in support of the Final Rules.

#### **B. Public Interest Amici's Interest In This Case**

Despite what many people believe, the patent system has extremely far reaching effects on all Americans. Specifically, undeserved patents and unsound patent policy harm the public by making products and services more expensive, if not completely unavailable, by preventing scientists from advancing technology, by unfairly prejudicing small businesses, and by restraining civil liberties and individual freedoms. Although the public can indeed benefit from a properly functioning patent system, since patents are nothing short of government sanctioned restraints on

freedom and competition, the public can also be severely harmed by errors within the patent system. For that reason, patent law and policy should be crafted with full knowledge of all of the effects, both positive and negative, the patent system has on all people.

Unfortunately, however, it is too often the case that not all of the interests affected by the patent system are adequately represented in patent policy discussions. Specifically, the interests of the non-patent holding public are almost always absent from any meaningful participation in decision making about the patent system, despite the fact that they can bear the brunt of its burdens. This lack of representation of the public interest is due in part to the fact that the patent community culture tends to dismiss and exclude the opinions of those it sees as unsophisticated outsiders, but it is mostly because the general public does not yet realize how much the patent system actually affects them. Regardless, the result is that the ears of judges hearing cases related to patent policy are too often monopolized by the concentrated group of special interests that benefit from an enlarged patent system, namely patent holders and patent attorneys, while the general public interest in favor of a more balanced patent system is rarely heard.

As with any body of law that applies to and affects all Americans, patent policy should be made with consideration of all of the public's interests, not just the specific interests of patent holders and patent attorneys. Thus, the Public Interest Amici intend to represent those otherwise underrepresented interests to the Court in this brief. The Public Interest Amici have no financial interest in any of the parties in this case and submit this brief solely because of 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 holders and patent attorneys.



## **II. THE PUBLIC INTEREST OVERWHELMINGLY SUPPORTS THE FINAL RULES**

The public interest overwhelmingly supports the USPTO's Final Rules for at least two significant reasons. First, they will enable the USPTO to curtail abuses of the patent application process made by those patent applicants who seek to pervert the system to gain an unfair advantage. Second, the Final Rules will help the USPTO improve patent quality, which is a critical issue for ensuring the patent system benefits the American public. As a result, since the public interest overwhelmingly supports the Final Rules, they are unquestionably reasonable and rational.

### **A. The Final Rules Will Enable The USPTO To Curtail Abusive Behavior By Exploitative Patent Applicants**

Despite Plaintiffs' characterization to the contrary, the Final Rules do not – in fact – “restrict” any of the rights of patent applicants under the law. Memorandum in Support of Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction, 9-11. Instead, they merely ask applicants to justify or lighten the burden placed on the USPTO by certain behavior that has been used by patent applicants in the past to seek an unfair advantage in the patent application process. After careful and lengthy consideration and deliberation by the USPTO, the Final Rules strike a fair and reasonable balance between preserving the rights of patent applicants to obtain all of the patent protection they deserve and ensuring that those patent applicants who want to game the system for undue advantage are thwarted in such attempts.

#### **1. The Final Rules Will Curtail Abuse Of Continuation Applications**

Continuation applications provide applicants who have had their patent applications finally rejected the ability to force the USPTO to revoke the finality of the rejection simply by paying a fee for a new filing. Thus, as one reference cited by the administrative record in this case found, it is

impossible for an examiner to ever actually finally reject a patent application so long as the applicant has sufficient financial resources to keep paying for continuation applications. Final Rules at 46718-19 (*citing* Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B. U. L. Rev. 63 (2004)). This results in USPTO examiners who have repeatedly rejected an application facing the possibility of an endless stream of continuation applications being filed by the applicant that “may well succeed in 'wearing down' the examiner, so that the applicant obtains a broad patent not because he deserves one, but because the examiner has neither incentive nor will to hold out any longer.” Lemley & Moore, 85 B. U. L. Rev. at 65. Such “wearing down” of examiners is an abhorrent abuse of continuation applications.

Applicants also abuse the continuation application process in other ways. Some monitor commercial actors who attempt to design around a previously issued patent and then submit claims in a much later filed continuation application that are directed specifically at those design-around efforts. *Id.* at 76-77. These applicants lie in wait until the commercial actor launches or otherwise commits to their design-around product and they then quickly get the USPTO to issue the continuation patent, which has a greater likelihood of ensnaring the commercial actor because its claims were written with the design-around product specifically in mind. As expressly discussed by the USPTO in the administrative record in this case, such perverse manipulation of the patent system is contrary to the public interest because it defeats the public notice function of patent claims, which in turn undermines investments made by commercial actors trying to avoid patent infringement. Final Rules at 46758 (*citing To Promote Innovation: The Proper Balance of Competition and Intellectual Property Law and Policy*, Ch. 4 at 26–31 (Federal Trade Commission

2003) and Lemley & Moore, 84 B. U. L. Rev. at 100).

Further, in its widely heralded 2003 report, the Federal Trade Commission (“FTC”) concluded, after holding hearings involving more than 300 panelists representing various interests in the patent system, that continuation applications can both “allow opportunistic behavior” and “disrupt competitive behavior.” *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Ch. 4 at 28 (2003) (“FTC Report”). Although the FTC found that proper use of continuations could serve legitimate functions, the FTC also found that the right to unlimited continuation applications without justification could be used in ways that were “harmful” to competitors. *Id.* Specifically, the FTC Report stated, “[b]y filing one or more continuing applications the applicant may extend the prosecution period – *and the potential for working mischief* by broadening claims – for years.” *Id.* at 27 (emphasis added). In conclusion, the FTC Report suggested that the problems with continuation applications should be remedied and recommended that any such remedy, “should protect legitimate uses of continuing applications, as well as deter anticompetitive uses of continuations.” *Id.* at 29.

For these and other reasons, the requirement contemplated by the Final Rules that applicants justify the need for more than two continuation applications is perfectly reasonable and rational. Such a requirement allows applicants to adequately claim patent coverage for their inventions, but does not allow for abusive procedural gamesmanship. If an applicant believes that they deserve a patent on an application that has been finally rejected by an examiner after all of the continuation applications they are entitled to file as a matter of right have been exhausted, they already have the right to pursue appeal to the Board of Patent Appeals within the USPTO.

35 U.S.C. § 134. And if they are unsatisfied with the result of that appeal, they also have the right to appeal that decision to the Federal courts. 35 U.S.C. § 141. Therefore, the curtailing of abusive use of continuation applications under the Final Rules would still afford applicants plenty of chances to get the patents that they deserve.

Plaintiffs and their supporting Amici proffer excuses for why they need to be able to file unlimited continuation applications without having to provide any justification for doing so after a certain threshold number have been filed. Specifically, they argue that they need to be free to add new claims in any number of continuation applications filed long after the original application was filed because it may take them that long to realize what it is that they want to claim. Memorandum in Support of Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction, 5. These excuses lack any technological or economic merit, because any claims desired and deserved by a patent applicant can and should be included in the original application, an amendment to it, or any of the continuation applications allowed under the Final Rules as a matter of right without justification. The failure to do so would be caused by the patent applicant's own delay in recognizing what it is they want to claim, and not by the USPTO or its Final Rules. Further, such applicants would still be able to petition to the USPTO to justify their need to obtain more continuation applications than the Final Rules allow as a matter of right. As such, any legitimate need for additional continuation applications would be fully satisfied.

## **2. The Final Rules Will Curtail Abuse Of Unlimited Claiming**

Similar to the abuse of continuation applications, some patent applicants also use the right to file an unlimited number of claims as a mechanism to over burden patent examiners. Simply

put, some applicants purposefully attempt to overwhelm the USPTO examiner by submitting dozens, if not hundreds, of claims in their application with the hope that the examiner will simply not have sufficient time to fully analyze and review each one. As a result, the application does not receive the same amount of attention per claim as an application with fewer claims would receive. Just as with the abuse of continuation applications, the ability to file an unlimited number of claims in an application provides patent applicants with a procedural method for burdening the examiner such that she is unable to perform as much scientific and technological analysis as she otherwise would absent such gamesmanship.

Thus, the Final Rules' requirement that patent applicants who seek more than a reasonable number of claims provide some assistance to the USPTO in reviewing that application for scientific merit is fair and in the public interest. The Final Rules do not in any way preclude applicants from applying for as many claims as they would like, nor do they take away any right granted to patent applicants under the Patent Act. Rather, all the Final Rules do is help the USPTO ensure that the patent application process is not susceptible to abuse by the submission of applications containing an inordinate number of claims.

#### **B. The Final Rules Will Help The USPTO Improve Patent Quality**

By helping the USPTO reduce wasted effort on unwarranted abuse of the patent application process, the Final Rules will free up staff and resources that can be used to improve patent quality, which is one of the most important issues for ensuring the patent system advances the public interest. The Final Rules will also aid patent quality directly because continuation applications and applications with more than twenty-five claims are more likely to result in the issuance of

undeserved patents than original applications or applications with twenty-five or fewer claims.

### **1. Patent Quality Is An Issue Of Utmost Importance To The Public**

As the Supreme Court has repeatedly recognized, including as recently as this past April, maintaining high patent quality is one of the most important issues on which to concentrate to ensure the patent system benefits the American people. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1746 (2007) (“the results of ordinary innovation are not the subject of exclusive rights under the patent laws ... [w]ere it otherwise patents might stifle, rather than promote, the progress of useful arts”) (*citing* U.S. Const., Art. I, § 8, cl. 8).

Patent quality is critical to a properly functioning patent system because patents that are undeserved can cause substantial harm to the public. This harm is caused by the fact that issued patents – regardless of their true legitimacy – can be used to threaten and impede otherwise permissible, socially desirable, conduct. *Id.* The threat of having to incur the costs and potential liability of a patent lawsuit is one that few individuals or small businesses can withstand, even if the patent is of doubtful validity. This chilling effect, when caused by a patent that would be ruled invalid if challenged, provides no social benefit to the American people, because the patent contains nothing new (its invalidity means that whatever it claims was already known or obvious in light of what was already known). This effect can be devastating to the American people.

For example, there have been several patents that were used to preclude competition in markets worth billions of dollars that were later proven to be undeserved. One industry where this phenomenon repeatedly occurs is the pharmaceutical industry. In one case, a patent used to prevent competition in the \$1.6B per year market for the cancer treatment paclitaxel (marketed by

Bristol-Myers Squibb under the brand name Taxol) was later proven invalid. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001). In another case, a patent used by Eli Lilly to bar commercial alternatives to its \$2.9B per year version of the antidepressant medication fluoxetine hydrochloride (marketed by Lilly under the brand name Prozac) was also proven invalid. *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955 (Fed. Cir. 2001). As these examples show, consumers of pharmaceuticals are especially prone to the negative effects of poor patent quality, as markets with monopolies maintained by undeserved patents force consumers to spend much more on drugs than they would if the market was subject to competition unrestrained by invalid patents.

Further, the over-patenting that results from low patent quality leads to thickets of patents that choke first inventors with countless small improvement patents claimed by others. In what is akin to grade-inflation, by granting too many people too many patents, those inventors who legitimately do derive wonderful new technology get less credit than they deserve because of all the other patents that are issued in the related field. This results in less incentive for the truest of innovators and instead encourages investments in making minor improvements to the inventions of others. These are, unfortunately, but a few of the many harmful effects that poor patent quality can have on the American public. To alleviate and prevent these harms, it is crucial that the USPTO be allowed to implement fair rules that will help it improve and maintain high patent quality.

## **2. By Increasing USPTO Efficiency, The Final Rules Will Improve Patent Quality**

A recent study showed that about one third of patent applications are continuations. Lemley & Moore, 85 B. U. L. Rev. at 69. This not only provides opportunities for the gamesmanship discussed above, but it also results in a significant amount of rework by patent

examiners, which adds substantial inefficiency into the patent application process. Another inefficiency in the patent application process caused by allowing patent applicants to file as many continuation applications as they would like without justification is that patent applicants are not compelled to focus their applications to what they have invented, because they know that they can always file continuation applications later to specify whatever it is they want to claim. Such unfocused prosecution results in the USPTO's examiners having a more difficult time analyzing the merits of pending applications.

In short, the Public Interest Amici agree wholeheartedly with the USPTO's statement recently made to the Court in this case that, “[w]hile this type of strategy may be advantageous to Plaintiffs and others, its effects on the efficiency of the USPTO are profound.” Defendants' Opposition to Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction, 10. As such, the requirement contemplated by the Final Rules that applicants justify the need for more than two continuation applications is perfectly reasonable and within the public interest. Such a requirement completely maintains the right of applicants to adequately claim patent coverage for their inventions while also creating a more efficient environment for the review of patent applications, thus allowing the USPTO to do a better job in less time.

Similarly, requiring patent applicants who seek more than a reasonable number of claims to provide some assistance to the USPTO in reviewing that application for scientific merit is fair and in the public interest. The Final Rules do not in any way preclude applicants from applying for as many claims as they would like, nor do they take away any right granted to patent applicants under the Patent Act. Rather, all the Final Rules do is help the USPTO ensure that the patent application



process stays efficient even when faced with applications containing dozens or hundreds of claims.

The improved efficiency at the USPTO created by the Final Rules will result in better patent quality, because more staff and resources can be directed to performing the critical task of technological and scientific analysis of patent applications. This will result in a significant public benefit, as the instances of poor patent quality, and the harms caused thereby, will be reduced.

### **3. Curtailing Abusive Use Of Continuations And Unlimited Claiming Will Directly Result In Improved Patent Quality**

As discussed above, the Final Rules implement a fair and reasonable process for curtailing abuse of continuation applications and the ability to file an unlimited number of claims. In addition to improving efficiency, another benefit of curtailing such abuse is that it will also directly improve patent quality. First, continuation applications, as compared with original applications, are more likely to result in patents that are undeserved. Lemley & Moore, 85 B. U. L. Rev. at 75. This is especially troubling because roughly half of all litigated patents, which generally have a greater impact on the public than non-litigated patents, result from continuations applications. *Id.* at 75-76.

Returning to the examples given above regarding the impact of poor patent quality on consumers of pharmaceuticals, the patents used to monopolize those markets that were ultimately held invalid by the courts were both the result of continuation applications. In the Taxol case, the patent proven to be invalid resulted from an application that was a continuation of a division of a grandparent application. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001). In the Prozac case, the patent proven to be invalid was a continuation-in-part of a continuation-in-part of a division of a great-grandparent application. *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955 (Fed. Cir. 2001). Thus, by ferreting out unjustified uses of continuation applications,

the Final Rules will help prevent such patents from issuing in the first place.

Second, examiners are more likely to erroneously allow claims that are undeserved in applications with over twenty-five claims than in applications with twenty-five or fewer claims. Defendants' Opposition to Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction, 20. As such, since the Final Rules will empower the USPTO to identify and eradicate abusive use of continuation applications and unlimited claiming, they will also help prevent undeserved patents from issuing in the first place. This result will substantially benefit the public.

**C. The Special Interests Of Patent Holders And Patent Attorneys Do Not Always Align With The Public Interest**

The *amici* briefs supporting the Plaintiffs at the preliminary injunction stage of this case manifested the traditional tendency to argue that the “public interest” is aligned with the interests of patent applicants, for whom lowered costs and maximized ability to take advantage of the patent application process may well be in their private interests. However, as economists Adam B. Jaffe and Josh Lerner observed in their landmark study of the patent system:

When issues of patent policy are considered by the courts, the Congress, and the Executive branch, you can be sure that the opinions of patent lawyers and patent holders will be heard. While their arguments will often be couched in terms of the public interest, at bottom their interest is in their own profits and livelihoods, not in designing a patent system that fosters the overall rate of innovation.

Adam B. Jaffe & Josh Lerner, *Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It*, Princeton University Press, 2004, p. 23. Thus, arguments regarding the public interest made by patent holders and patent attorneys should be carefully scrutinized, because they are, in fact, the special interests that benefit from the patent system and what benefits them personally may not actually benefit the public interest.

To be sure, while there is indeed a strong public interest in supporting innovation, that does not mean that incentives for patents should always be raised without considering the corresponding cost to society. Congress has intentionally implemented a patent system that balances the incentives provided to patentees with the benefit to the public of the disclosure and ultimate dedication of the resulting inventions to society. Thus, the public interest lies in an efficiently functioning patent system, not one that is subject to abuse and manipulation. Since the Final Rules will help the USPTO achieve this goal, they are in the public interest.

### **III. EQUITY ALSO FAVORS THE USPTO AND THE FINAL RULES**

In addition to the public interest being in support of the Final Rules, equity also favors the USPTO in this case. This is because, despite what the Plaintiffs may lead the Court to believe, this case is not the first time the USPTO has promulgated rules of its own initiative that affect currently pending patent applications. Just in the past five years the USPTO implemented rules that prohibited supplemental patent owner responses without a showing of sufficient cause (See 72 Fed. Reg. 18892 *et seq.*) and declared that supplemental replies would no longer be entered as a matter of right (See 69 Fed. Reg. 56482 *et seq.*). The former is particularly analogous to the Final Rules, except for the fact that the previously implemented rules were actually *more* restrictive on currently pending patent applications in that they required *all* supplemental responses to show sufficient cause. In contrast, the Final Rules only affect continuation practice after the first two “as a matter of right” continuations are exhausted by the applicant. The previously implemented rules are also of note because, as in this case, in neither of those previous situations was the USPTO spurred to promulgate those rules by the need to conform to any new legislation.

In each case described above, the new rules went into effect on time and without any litigation against the USPTO. As such, the true status quo is that the USPTO can indeed put into effect rules of its own initiative that affect the rights of pending patent applicants. The Plaintiffs' attempt in this case to characterize this status quo as "illegal" (GSK Complaint, ¶117) is undermined by the fact that neither they nor any other party ever challenged the USPTO's rule making authority prior to this case. Thus, equity in this case actually favors the USPTO and, thus, opposes the granting of any permanent injunction barring implementation of the Final Rules.

#### IV. CONCLUSION

For the reasons set forth above, the Public Interest Amici respectfully submit that the Court should grant the USPTO's anticipated motions for summary judgment.

Respectfully submitted,

*Of Counsel*

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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*

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 BRIEF FOR *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 IN SUPPORT OF DEFENDANTS' ANTICIPATED MOTIONS FOR SUMMARY JUDGMENT 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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