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

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

CONSOLIDATED WITH

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

BRIEF OF *AMICUS CURIAE* THE PENNSYLVANIA GREENHOUSES IN SUPPORT OF PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

I. INTRODUCTION

The Biotechnology Greenhouse Corporation of Southeastern Pennsylvania ("BioAdvance"), the Life Sciences Greenhouse of Central Pennsylvania, and the Pittsburgh Life Sciences Greenhouse (collectively, the "Pennsylvania Greenhouses") submit this brief as *amicus*

curiae in support of the motions for summary judgment by the Plaintiffs Tafas et al. and SmithKline Beecham Corp. et al. (collectively the "GSK Plaintiffs") in the above-captioned case. Like the GSK Plaintiffs, the Pennsylvania Greenhouses oppose implementation of the Final Rules published by the United States Patent and Trademark Office ("PTO") on August 21, 2007 as 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) (hereinafter "Final Rules") (to be codified at 37 C.F.R. pt. 1).

The Pennsylvania Greenhouses are fully aware that the Court has received many pleadings and papers from the GSK Plaintiffs and the PTO, as well as from *amici curiae* BIO, AIPLA, Elan, and others. Indeed, the Pennsylvania Greenhouses agree with the factual statements and legal arguments presented by the GSK Plaintiffs, as well as *amici curiae* BIO, AIPLA, and Elan in their respective filings to date. However, the Pennsylvania Greenhouses are uniquely situated to present this Court with an important additional perspective—that of a state-funded entity charged with fostering grass-roots economic development in the early-stage life science industry using state-derived funds. Therefore, the Pennsylvania Greenhouses desire to participate as *amicus curiae*, and will focus this brief primarily on the arbitrary nature of the Final Rules, the public interest in promoting and protecting the innovative efforts of small or emerging life science companies and the irreparable harm that would result from implementation of the Final Rules.

As will be more fully explained below, the Final Rules will cause irreparable injury not only to the GSK Plaintiffs, but also to the Pennsylvania Greenhouses and early-stage companies having a property interest in pending and future patent applications filed with the

PTO. The adverse effects of the Final Rules will be felt most strongly in the life science industry, especially in early-stage companies. The Final Rules will profoundly and adversely impact early-stage funding and economic development organizations, such as the Pennsylvania Greenhouses.

The life science industry relies heavily on the patent process and the current, established PTO rules of practice to obtain adequate protection for its inventions and to attract the necessary financial investment to research, develop, and commercialize life science products. Due to the scientific and regulatory complexity of the life science industry, those products often take more than a decade to reach the market, and require many years of sales to recover the necessary financial investment. The Final Rules threaten not only the right of early-stage companies to obtain adequate patent protection, but also threaten adequate patent protection as a critical incentive for seed funding of such companies. Seed funding is a scarce resource, as reflected by the creation of public-private partnerships like the Pennsylvania Greenhouses, state economic development initiatives, and other specialized early-stage investment vehicles.

II. BACKGROUND

The Pennsylvania Greenhouses were founded in 2002 using $100 million in funds paid to the Commonwealth of Pennsylvania resulting from settlements between the Commonwealth and various tobacco companies. *See* Exhibit 1, Declaration of Barbara S. Schilberg, Exhibit 2, Declaration of Mel Bilingsley, and Exhibit 3, Declaration of John W. Manzetti. The Pennsylvania legislature established the Pennsylvania Greenhouses as a public-private partnership to promote the establishment and growth of life science companies in Pennsylvania. *Id*. Importantly, the directive and mission of the Pennsylvania Greenhouses is to

advance the life sciences and to improve lives through improved healthcare and enhanced economic opportunity. *Id*. To date, the Pennsylvania Greenhouses have funded, or caused to be funded, over 100 new and expanding early-stage life science companies. *Id*. In turn, the Pennsylvania Greenhouses have created new technologies and hundreds of jobs in the Commonwealth of Pennsylvania. *Id*. In addition to the Declarations attached hereto, the following sections further describe the three Pennsylvania Greenhouses and provide examples of the companies in which the Pennsylvania Greenhouses have invested funds and resources.

A. BioAdvance, The Biotechnology Greenhouse of Southern Pennsylvania

BioAdvance invests in companies developing therapeutic agents, diagnostics, and devices to improve human health. *See* Exhibit 1, Declaration of Barbara Schilberg and Appendix A thereof. BioAdvance invests up to $1 million per company in emerging life science companies, and provides many business services to those companies. *Id*. at ¶ 4. Since 2003, $11.5 million has been invested in 21 companies and nine pre-seed projects by BioAdvance. *Id*. at ¶ 6. In turn, the investment partners of Bioadvance have raised almost $200 million in additional capital. *Id*. Representative early-stage company investments include Avid Radiopharmaceuticals, Inc., which is developing novel radiopharmaceuticals for early diagnosis of Alzheimer's disease; Protez Pharmaceuticals, Inc., which seeks to discover novel antibiotics to combat drug resistance in difficult-to-treat hospital-based infections; and Gelifex, Inc., which has developed novel spine implants for degenerative disc disease. *Id*. Other activities and information concerning BioAdvance and companies funded by BioAdvance are described in Exhibit 1 and Appendix A thereof.

B. Life Sciences Greenhouse of Central Pennsylvania

The Life Sciences Greenhouse of Central Pennsylvania ("LSGPA") seeks to improve human health and provide a strong base for regional business investments. *See* Exhibit 2, ¶ 3. LSGPA typically invests up to $1 million in novel life sciences technologies with strong market potential that are complemented by robust intellectual property profiles. *Id*. at ¶ 4. LSGPA has invested $9 million in seed and pre-seed stage capital, nearly $3.7 million in small businesses and university-based initiatives for the refinement of cutting edge technologies, and $3.4 million dollars committed to relocation efforts and the build-out of incubators with wet lab space. *Id*. at ¶ 5. Representative early-stage company investments include Azevan, Inc., which is developing novel vasopressin antagonists for cardiovascular and CNS diseases; Chaperone Technologies, Inc., which seeks to discover new antibacterial medicines; Hanson Technologies, Inc., which is developing integrated biological and chemical sensors; and NanoHorizons, Inc., which manufacturers and develops nanoparticles and nanofilms—a promising technology for the advancement of biotechnology. *Id*. Other activities and information on LSGPA and companies funded by LSGPA are described in Exhibit 2 and Appendix A thereof.

C. Pittsburgh Life Sciences Greenhouse

The Pittsburgh Life Sciences Greenhouse ("PLSG") provides entrepreneurial life science enterprises in Pittsburgh and southwestern Pennsylvania with the resources and tools they need to make global advances in research and patient care. *See* Exhibit 3. PSLG can invest up to $1 million in portfolio companies. *Id*. at ¶ 4. Since 2002, PLSG has committed over $9.5 million in 47 life science companies, which have attracted $300 million in follow-on additional capital. *Id*. at ¶ 5. Representative early-stage company investments include Cardiorobotics, Inc.,

which is a medical device company focusing on highly articulated robotic probes; Cellatope Corp., which is developing diagnostics for auto-immune diseases such as lupus; and Immunetrics, which provides tools for drug discovery and clinical diagnostics of inflammatory diseases. *Id*. Other activities and information concerning PSLG and companies funded by PLSG are described in Exhibit 3 and Appendix A thereof.

D. Patent Protection Is Vital to The Companies in Which The Pennsylvania Greenhouses Invest

Companies funded by the Pennsylvania Greenhouses are involved in researching and developing products across a wide array of life science technology areas, including healthcare pharmaceuticals, diagnostics, therapeutics, food and agriculture, and environmental protection. *See*, for example, Exhibit 1, ¶ 6, *see also*, Exhibit 2, ¶ 6, and Exhibit 3, ¶ 7. Patent protection is vital to the companies in which the Pennsylvania Greenhouses invest, and funding decisions are based in large part on each company's ability to obtain patents. *Id*. at ¶ 7. The ability to obtain clear and comprehensive patent protection is a key element in attracting necessary initial capital investment, as well as corporate partners necessary to commence the costly research and development of life science inventions. *Id*. at ¶ 8. In turn, sustaining adequate and ever-increasing levels of financing and partnering during continued research and development, clinical investigations, regulatory approval, and commercialization of a life science product depends upon a funded company's ability to obtain comprehensive patent protection. *Id.* The ability of an early-stage life science company to obtain capital is directly tied to its intellectual property assets and particularly to its patent portfolio. *Id*. This fact simply cannot be overstated.

In addition, continuations practice is more prominent with respect to life science patents than those in other technology areas, such as electronic and mechanical patents. *See*, Exhibit 4, ¶ 6, Declaration of Kurt L. Ehresman. Further, continuations practice is particularly critical for early-stage life science organizations, whose platform technologies typically develop from a single innovation in a limited field of science. *Id*. In light of these unique circumstances, the Final Rules will have a disparate impact on the early-stage companies and their investors, such as the Pennsylvania Greenhouses.

III. ARGUMENT

A. The Final Rules Violate The Patent Act Because They Are *Ultra Vires*

The PTO should be permanently enjoined from implementing the Final Rules because they exceed the PTO's statutory authority under the Patent Act, 35 U.S.C. §120. Like GSK and *amicus* party Elan, the Pennsylvania Greenhouses assert that the Final Rules are *ultra vires* because the PTO lacks substantive rulemaking power, and because the Final Rules retroactively change the consequences of applications that have already been filed based on the current laws. *See Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (expressly recognizing limitations upon the PTO's power to issue substantive rules). In particular, it is clear that the new Rule 1.78 exceeds the plain language of Section 120 of the Patent Act. 35 U.S.C. § 120. Section 120 of the Patent Act permits patent applicants to file an unlimited number of continuation applications that relate back to the filing date of the original application. *Id.* In this regard, the statute expressly states that an "application for patent for an invention disclosed … in

an application previously filed in the United States … *shall have the same effect*, as to such invention, as though filed on the date of the prior application ….” *Id.* (emphasis added). There is nothing in the language of that statute that gives the PTO the authority to limit the number of continuation applications or to deprive applicants the right of priority granted to such applications under Section 120. Rule 1.78 as amended seeks to arbitrarily limit continuation patent applications in number and to add additional requirements for filing a continuation which are not found in or authorized by statute.

In amending Rule 1.78 in the Final Rules, the PTO arbitrarily restricts applicants to only *two* continuation applications without the need for filing a petition and making a special showing that the amendment, arguments, or evidence could not have been submitted during the prosecution of the two prior-filed applications. 72 Fed. Reg. at 46839. If this special showing cannot be satisfied, then the subsequent application will lose the benefit of priority that it otherwise would have been entitled to under Section 120 of the Patent Act.

Plainly, the amendment to Rule 1.78 of the Final Rules is an effort to administratively cause a forfeiture of substantive rights granted by Congress, and is invalid. *See, Merck*, 80 F.3d at 1549-50 (expressly recognizing the limitations upon the PTO’s power to issue substantive rules); *In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968) (stating that the PTO has “no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of copending applications, provided applicant meets all the other conditions of the statute”). The PTO must comply with the language of the statute, which does not limit the number of continuation applications. Additionally, and for all the reasons stated by the GSK

Plaintiffs and Elan in their pleadings and papers, the Final Rules are *ultra vires* and impose arbitrary and capricious requirements which cause the loss of substantive patent rights granted by statute, and must be permanently enjoined.

B. The Final Rules Improperly Place An Increased and Undue Burden on Patent Applicants, and Particularly on Early-Stage Life Science Companies

The Final Rules improperly shift the burden of examination onto patent applicants. Implementation of the Final Rules will cause irreparable harm to life science industries, and will negatively impact the public interest in promoting innovation, particularly on early-stage life science companies. The increased and undue burden involves, among other things, abandonment of current, established PTO rules of practice and associated time-tested patenting procedures that provide adequate and necessary patent protection for pharmaceuticals and other life science inventions. The Final Rules will also unduly burden early-stage companies through increase patent prosecution costs, including increased costs of patent attorney's fees and PTO fees that will result from the proposed Final Rules.

Additionally, a very real burden that no party has yet voiced to the Court involves the adverse impact the rules will have on early-stage capital investments, which are the very lifeblood of early-stage companies. The Final Rules will remove existing incentives to investment in early-stage companies. For early-stage and emerging life science companies facing long product development and regulatory approval timelines, any loss of capital investment can be fatal. That is particularly true given the current scarcity of venture capital available to such companies in the current economic environment.

1. The Final Rules Will Force Applicants to Abandon Current, Established PTO Rules of Practice and The Corresponding Time-Tested Patenting Process

The Final Rules will adversely and irreparably affect life science organizations' ability to adequately protect their inventions and to secure and maintain necessary funding for their research and development efforts. For many years, life science companies have relied upon the certainty of current, existing patent rules in filing patent applications, and in the current continuation rules to obtain protection for their inventions. *See* Exhibit 4, ¶ 6. However, as noted, the Final Rules will have a disparate impact on life science organizations because continuations practice is more prominent in the life sciences area than in others. *Id*. For example, as explained in the GSK Brief, in the *amicus* briefs by Elan, and in the Battle Declaration, the certainty of available continuations has enabled drug development companies to investigate various uses of patented classes of drug compounds and to patent the later-refined uses of those compounds and dosage formulations for particular diseases via continuation applications of the earlier patent application. That time-tested and productive patenting procedure has been responsible for building many great life science companies, such as GSK, Elan, and others. In turn, the availability of continuation patent applications has attracted investors, who provide capital for further research and development, spurring the life science industry to the benefit of all.

In contrast, as evidenced by the present litigation and the numerous comments in the administrative record, the Final Rules are expected to force a sea change in the certainty of current patent practices and particularly patents in the life science industry. The Final Rules have profound implications for early-stage companies, which have neither the funds nor the

longevity to wade into the new Final Rule seas. These companies need the certainty of patents to obtain lifeblood investment of capital. *See* Exhibits 1-3, *see also* Battle Decl. ¶ 12.

If an early-stage company cannot rely upon the certainty of more than two continuation patents and a single RCE as proposed in the Final Rules, it will be forced to guess as to which invention in its initial patent disclosure will survive the rigors of development and testing. Such guessing is nearly impossible, especially for pharmaceuticals, due to the unpredictable efficacy, side effect, safety, and formulation characteristics that can only be determined through lengthy and expensive testing over a period of many years. In short, the new, arbitrary limitations on continuations will prohibit patenting in the late stages of product development—just when the scope of necessary patent protection becomes clearly visible, and just when the threat of competition becomes imminent. That combination is a recipe for failure, especially for emerging life science companies which typically develop from a single innovation and have few products in development. *See* Exhibit 4, ¶ 6. That failure of meaningful patent protection will ultimately prevent the development and commercialization of technological advances for the diseases and other health problems facing Pennsylvanians, citizens of this country, and mankind in general.

2. The Final Rules Arbitrarily and Impermissibly Ignore The Realities of Past and Current PTO Patent Practice Concerning Continuations and RCEs

The Final Rules arbitrarily and impermissibly ignore the realities of past and current PTO patent practice concerning continuations and RCEs. The Court should note that the patent application process is highly subjective, and is ultimately controlled by one absolutely unpredictable factor—human discretion. *See* Exhibit 4, ¶ 8. The interpretation and application

of patent law, PTO rules, and PTO procedure and policy vary unpredictably among patent examiners, PTO art units, the PTO Office of Petitions, and the Board of Patent Appeals and Interference. At each stage of patent prosecution, restriction practice, and appeals, discretion is exercised by persons having individual personalities, proclivities, experiences, and opinions. While some of those factors can be controlled through supervision, training, and the PTO appeal processes, none of those factors can be eliminated.

The Pennsylvania Greenhouses accept that this human element is irreplaceable. However, to balance the human element, flexibility in patent practice has always been available, and must continue to be available to avoid arbitrary capricious, or inappropriately mechanical results. When a patent application involves complex new and innovative technologies, which is often the case with life sciences applications, an applicant filing that application needs every opportunity to meet his burden of proving novelty and non-obviousness. It often takes multiple filings of continuations and RCE's simply to resolve issues raised by the PTO, educate the patent examiner(s) as to the nature of the invention and its technology, and come to a mutual understanding concerning the teachings of prior art and the routine skill of those practicing it. Only then can the PTO determine that the application deserves a patent. Indeed, frequently more than two continuations and RCE patent applications are necessary to secure a single issued patent for a single invention. *See* Exhibit 4, ¶ 7. *Id.* Strategically, applicants also often accept significantly narrowed claims at the outset in order to have a patent issued. This ongoing process allows the applicant the benefit of having an issued patent in its portfolio, which is desirable when seeking funding from investors like the Pennsylvania Greenhouses, while providing the company an opportunity to pursue separately, in a continuation application, the broader claims

that it is legally entitled to. The current continuation practice also allows applicants to conduct further research to provide the examiner with requested data in order to overcome PTO rejections. For example, a declaration under 37 C.F.R. § 1.132 to overcome an obviousness rejection may not be considered by an examiner unless there are comparative data between the art cited and the method of the invention. This takes time and requires an RCE or continuation to present the data to the PTO. Also, in view of the recent decision in *KSR v. Teleflex,* 550 U.S. ___, 127 S. Ct. 1727 (2007) (concerning obviousness as applied to patent claims), such declaration practice is likely to become a more common practice. The PTO's arbitrary and mechanical rules limiting continuation practice curtail applicants' right to receive the protection of their inventions that they are legally entitled to. To handle these and other situations, patent applicants should be permitted to exercise flexibility, such as accepting narrower claims than those to which they may be entitled and filing continuations to seek broader claims, without having to surrender continuation patent applications that would have been directed to other patentable subject matter disclosed in the parent application.

The Final Rules, however, do not recognize or permit the flexibility that is present and necessary to balance the various complex factors including the human element inherent in PTO practice. Rather, the Final Rules attempt to shoehorn the entire patent application process into an arbitrary maximum of two continuations, one RCE, as well as to impose arbitrary claim number limits and self-examination requirements that burden applicants with additional duties that have heretofore always been the PTO's responsibility.

3. The Proposed Rules Will Increase Patent Costs and Have An Adverse Effect on Investment in Early-Stage Life Science Companies

Life science product development is not only unpredictable and time-consuming, it is also extremely expensive. *See* Exhibits 1-3; *see also* Battle Decl. ¶ 15. Companies engaged in developing those products are heavily dependent upon patent protection to provide secure market exclusivity for any inventions, which will permit recovery of the significant investments involved in product development. *Id.* The companies funded by the Pennsylvania Greenhouses are no exception. However, it is important to note that investors, and particularly early-stage seed investors such as the Pennsylvania Greenhouses, also rely on the patent system to permit recovery of investments in research and development. *Id.*

Funding by the Pennsylvania Greenhouses in early-stage life science companies depends, in large part, on a company's potential and ability to obtain patents on the technologies and products that it has developed. *Id.*, *see also* Battle Decl. ¶ 18. That ability particularly includes potential for continuation patent applications to allow the company to maintain patent protection over its discoveries as products continue to be developed, refined, and approved. *Id.* If a life science company were to lose its basic patent coverage or be forced to give up the protections afforded by current continuation practice, the Pennsylvania Greenhouses and other investors would likely decline the next stage or round of investment because of the loss of exclusivity for the product and the resulting threat of competition. *Id.* Clearly, the Final Rules, and particularly proposed Rule 1.78, threaten a sea change in PTO patent practice that will force life science companies to give up currently available continuations and patent claims protections, and will remove the incentive for investment in early-stage companies by investors such as the Pennsylvania Greenhouses. The Final Rules threaten an arbitrary and impermissible change to

current patent practices that would ultimately stall the momentum of very significant life science economies and economic development initiatives such as that established by the Pennsylvania Greenhouses.

In addition to the loss of investment, the attendant legal costs will substantially increase in fees for patent services and will unduly burden early-stage patent applicants. Early-stage companies who have filed patent applications before November 1, 2007 will incur legal fees to renew and revise the applications to conform to the new Final Rules, and to reconsider patent prosecution procedures. For example, the new petition fee to request leave to file additional continuations or RCE's is higher than the filing fee for a new utility patent application. Accordingly, the Final Rules are expected to increase both fees for legal services, as well as fees charged by the PTO. These increased costs come at the worst possible time for early-stage companies, whose funding typically does not include money to cover the unexpected costs.

4. The Requirement of A Special Showing and The Realities of PTO Petitions Process Create A Dead End for Patent Applicants Seeking More Than Two Continuations

Even if the Court disagrees with arguments made by the Plaintiffs and *amici* concerning the *ultra vires* and arbitrary nature of the Final Rules limiting continuations and the number of claims in patent applications, the Pennsylvania Greenhouses ask the Court to consider the practical result of the Final Rules. The language of Final Rule §1.78(d)(vi) and the PTO's own responses to inquires made during the comment period clearly illustrate that virtually no foreseeable set of circumstances will meet the requirement of a "special showing." *See, e.g.* 72 Fed. Reg. 46767-79 (discussing how the office will decide petitions); *see also*, "Frequently

Asked Questions" at 20-21 (providing a list of factors the PTO will take into consideration for a petition).

Moreover, should an applicant act imprudently and submit a petition setting forth arguments in support of a special showing, they will encounter another problem at the PTO: It is no secret at the PTO and among patent practitioners that petitions result in delays, confusion, and inconsistent handling of patent applications. *See,* Exhibit 4, Declaration of Kurt L. Ehresman, and Appendix A thereto. The PTO has so many rules requiring petitions that it has created a separate Office of Petitions. Nonetheless, even having established such an office, the PTO by its own accounting since 2005 has experienced large petition backlogs. For example, according to the PTO's FY2007 Annual Report, the number of petitions involving most substantive matters of law has steadily increased. *See*, Appendix B to Exhibit 4. Curiously, that PTO Annual Report fails to report the extent of the backlog of petitions regarding patent matters, but it is obvious from the PTO's performance that decisions on patent petitions can take months or years. *Id.*

Even assuming that an applicant receives a timely response to a petition, there is no guarantee that the examiner will properly receive or consider the decision. For example, one of the most inventor-friendly petitions includes Petitions to Make Special, which specifically provides for expedited handling by the PTO of patent applications, such as those involving old inventors, ill inventors, and actual infringement by others. *See* 37 C.F.R. §1.102. In addition to improper handling, practitioners have encountered lengthy delays by the PTO. *See*, Appendix A to Exhibit 4. Indeed, in some instances the filing of a Petition to Make Special results in the perverse outcome of a <u>delay of examination</u> of the pending application. *See* Exhibit 4 ¶ 11. In short, the circumstances and performance of the PTO in handling petitions clearly demonstrate

that the proposed petitions process requiring special showings is likely to be ineffective to remedy the loss of substantive rights resulting from implementation of amended Rule 1.78 of the Final Rules, and truly represents a dead end for applicants seeking any more than two continuations under the Final Rules.

IV. CONCLUSION

The Final Rules violate the Patent Act as *ultra vires*. Additionally, the Final Rules arbitrarily and unnecessarily burden patent applicants, particularly applications pertaining to inventions in the life sciences. The purported remedy provided by Rule 1.78 (d)(vi) is illusory.

WHEREFORE, for the reasons stated herein and in its accompanying Exhibits, the Pennsylvania Greenhouses respectfully request that the Court grant the Plaintiffs' summary judgment motions and permanently enjoin the PTO from enforcing the Final Rules.

Respectfully submitted,

/s/

Robert C. Gill
VA Bar #26266
Counsel for *Amicus Curiae*
The Pennsylvania Greenhouses
SAUL EWING LLP
2600 Virginia Avenue, NW
Suite 1000 – The Watergate
Washington, DC 20037-1922
Telephone: (202) 295-6605
Facsimile: (202) 295-6705
rgill@saul.com

Of Counsel for Amicus Curiae
The Pennsylvania Greenhouses:

Kurt L. Ehresman
PA Bar #77707
USPTO Reg. No. 50758
SAUL EWING LLP
Penn National Insurance Plaza
2 North Second Street, 7th Floor
Harrisburg, PA 17101-1619
Telephone: (717) 257-7572
Facsimile: (717) 237-7431
kehresman@saul.com

Konstantina M. Katcheves
Admitted in MD
USPTO Reg. No. 54818
SAUL EWING LLP
Lockwood Place
500 E. Pratt St., 9th Floor
Baltimore, MD 21202-3100
Telephone: (410) 332.8685
Facsimile: (410) 332-8085
kkatcheves@saul.com

ATTORNEYS FOR *AMICUS CURIAE*
THE PENNSYLVANIA GREENHOUSES

December 27, 2007

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of December 2007, I caused a copy of the foregoing Brief of *Amicus Curiae* The Pennsylvania Greenhouses in Support of Plaintiffs' 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:

Elizabeth M. Locke
Kirkland & Ellis LLP
655 15th Street, NW - Suite 1200
Washington, DC 20005
Email: elocke@kirkland.com

and

Craig C. Reilly
Richard McGettigan Reilly & West PC
1725 Duke Street - Suite 600
Alexandria, VA 22314
Email: craig.reilly@rmrwlaw.com

Counsel for GSK Plaintiffs

Joseph Dale Wilson, III
Kelley Drye & Warren LLP
Washington Harbour
3050 K Street, NW - Suite 400
Washington, DC 20007
Email: jwilson@kelleydrye.com

Counsel for Plaintiff Tafas

Lauren A. Wetzler
United States Attorney's Office
2100 Jamison Avenue
Alexandria, VA 22314
Email: lauren.wetzler@usdoj.gov

Counsel for Defendants

Thomas J. O'Brien
Morgan, Lewis & Bockius
1111 Pennsylvania Avenue, NW
Washington, DC 20004
Email: to'brien@morganlewis.com

Counsel for Putative Amicus American Intellectual Property Lawyers Association

Dawn-Marie Bey
Kilpatrick Stockton LLP
700 13th Street, NW - Suite 800
Washington, DC 20005

Counsel for Putative Amicus Hexas, LLC, The Roskamp Institute, Tikvah Therapeutics, Inc.

James Murphy Dowd
Wilmer Cutler Pickering Hale & Dorr LLP
1455 Pennsylvania Avenue, NW
Washington, DC 20004
Email: james.dowd@wilmerhale.com

Counsel for Putative Amicus Pharmaceutical Research and Manufacturers of America

Randall K. Miller
Arnold & Porter LLP
1600 Tysons Boulevard - Suite 900
McLean, VA 22102
Email: Randall.Miller@aporter.com

Counsel for Putative Amicus Biotechnology Industry Organization

Respectfully submitted,

/s/
Robert C. Gill
VA Bar #26266
Counsel for *Amicus Curiae*
The Pennsylvania Greenhouses
SAUL EWING LLP
2600 Virginia Avenue, NW
Suite 1000 – The Watergate
Washington, DC 20037-1922
Telephone: (202) 295-6605
Facsimile: (202) 295-6705
rgill@saul.com