

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)

**MEMORANDUM OF *AMICUS CURIAE* THE PENNSYLVANIA GREENHOUSES
IN SUPPORT OF MOTION FOR LEAVE TO FILE A BRIEF IN SUPPORT
PLAINTIFFS' ANTICIPATED MOTIONS FOR SUMMARY JUDGMENT**

BioAdvance, the Life Sciences Greenhouse of Central Pennsylvania, and the Pittsburgh Life Sciences Greenhouse (collectively, the "Pennsylvania Greenhouses") submit this memorandum in support of their motion for leave to file a brief as *amicus curiae* in support of the anticipated motions for summary judgment by the Plaintiffs in the above-captioned consolidated cases. As described more fully below, the Pennsylvania Greenhouses and their

affiliates have a substantial interest in this litigation, and, as a representative of state-funded investors, promoters and supporters of the life sciences industry, the Pennsylvania Greenhouses can provide the Court with a unique and very important perspective on the issues.

The final rules published by the Patent and Trademark Office (“PTO”) on August 21, 2007, significantly alter patent applicants’ ability to claim and protect their innovations. 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 adverse effects of the Final Rules will no where be felt more strongly than in the life sciences industry, and especially in the early-stage companies, specifically those funded by investors such as the Pennsylvania Greenhouses. This life sciences industry relies heavily on patent protection, as well as the current, established PTO rules of practice, to obtain adequate coverage 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 Pennsylvania Greenhouses are deeply concerned about the irreversible loss of patent rights and the disincentives to innovation that the Final Rules will cause. The many changes in the PTO’s rules of practice will cause changes to the patent prosecution strategies of many early stage life sciences organizations, with a concurrent increase in fees for legal services. Should the Final Rules be implemented and enforced, those effects will further increase, placing an even heavier burden on early stage companies having scarce financial resources.

The Pennsylvania Greenhouses are uniquely positioned to provide the Court with information and perspective on the Final Rules' impact on early stage, state-funded life sciences organizations that the parties cannot, or may not have the incentive to, provide. The Pennsylvania Greenhouses, therefore, should be granted leave to submit an *amicus curiae* brief in support of the plaintiffs at the summary judgment stage of these proceedings.

I. BACKGROUND

The Pennsylvania Greenhouses were founded in 2002 to promote the establishment and growth of life science companies in Pennsylvania. However, more important, the mission of the Pennsylvania Greenhouses is to advance the life sciences and to improve the lives of Pennsylvanians through improved healthcare and enhanced economic opportunity. To date, the Pennsylvania Greenhouses have funded and caused to be funded many life science companies, and have provided business support services to those organizations. In turn, the Greenhouses have fulfilled the promise that they were hoped to have—the creation of many new jobs in the Commonwealth of Pennsylvania.

Companies funded by the Pennsylvania Greenhouses are involved in researching and developing products across a wide array of technology areas, including food and agriculture, healthcare, pharmaceuticals, diagnostics, therapeutics, and environmental protection. The companies funded by the Pennsylvania Greenhouses are early development-stage companies that have yet to achieve profitability, and that are years from bringing their technologies to market. *Patent protection is vital to these companies.* The ability to obtain clear and comprehensive patent protection attracts the capital and corporate partners necessary for the costly and lengthy development, approval, and marketing process for life science inventions. In turn, sustaining the

necessary level of financing and partnering depends on the ability to develop comprehensive patent protection for investigational products.

Furthermore, continuations practice is more prominent with respect to life sciences patents than those in other technology areas, such as electronic and mechanical patents. Further, continuations practice is particularly critical for emerging life sciences organizations, whose platform technologies typically develop from a single innovation in a limited field of science. In light of these unique circumstances, the Final Rules will have a disparate impact on the Pennsylvania Greenhouses and the life science companies in which they invest money derived from the Commonwealth of Pennsylvania.

The GSK Plaintiffs comprise a global pharmaceutical company that is not funded by the Pennsylvania Greenhouses. Plaintiff Tafas is an individual, who is also not funded by the Pennsylvania Greenhouses. As described above, the Pennsylvania Greenhouses represent a state-funded public-private partnership that funds a very diverse array of early stage life science organizations, whose limited personal and financial capital is invested in research and patents for inventions that are not limited to pharmaceuticals and health care. Further, the Pennsylvania Greenhouses have no stake in the GSK Plaintiffs, or any of the other parties to this litigation. Rather, the Pennsylvania Greenhouses represent interests consistent with, yet unique from, the current parties, which will be irreparably harmed if they are not permitted to challenge the proposed PTO rules by participating as *amicus curiae*.

A. BioAdvance, The Biotechnology Greenhouse of Southern Pennsylvania

BioAdvance invests in companies developing therapeutic agents, diagnostics and devices to improve human health. Since 2003, \$11.5 million has been invested in 21 companies and nine pre-seed projects. In turn, these investment partners of Bioadvance have raised almost \$200 million in additional capital since that time. Representative 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.

B. Life Sciences Greenhouse of Central Pennsylvania

The Life Sciences Greenhouse of Central Pennsylvania seeks to improve human health and provide a strong base for regional business investments. It 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. Representative investments include Acies, Inc., which acquires, develops, and markets products for burns and wound care; 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.

C. Pittsburgh Life Sciences Greenhouse

The Pittsburgh Life Sciences Greenhouse provides entrepreneurial life sciences enterprises in Pittsburgh and southwestern Pennsylvania with the resources and tools they need to make global advances in research and patient care. Since 2002, it has committed over \$9.5 million in 47 life sciences companies, which have attracted \$300 million in follow-on funding. Representative 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.

II. ARGUMENT

A. Legal Standard.

The decision whether to allow a non-party to participate as *amicus curiae*, and the extent and manner of such participation, is within the court's discretion. *Cobell v. Norton*, 246 F. Supp. 2d 59, 62 (D.D.C. 2003). The court may allow participation by an *amicus* "if the information is 'timely and useful.'" *Waste Mgmt. of Pa. v. City of York*, 162 F.R.D. 34, 36 (M.D. Pa. 1995). "An amicus brief should normally be allowed . . . when the amicus has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide," *Cobell*, 246 F. Supp. 2d at 62 (quoting *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir. 1997)), or when the *amicus* can "offer insights not available from the parties," *Citizens Against Casino Gambling in Erie County v. Kempthorne*, 471 F. Supp. 2d 295, 311 (W.D.N.Y. 2007) (quotations omitted).

B. The Pennsylvania Greenhouses Should Be Permitted to Participate as An *Amicus Curiae* Because They Represent Interests That Are Truly Unique That The Parties Cannot Provide.

The Pennsylvania Greenhouses' *amicus* brief would address the public interest prong of the plaintiffs' requests for injunctions permanently enjoining the implementation of the Final Rules and other issues raised by the parties during summary judgment about which the Pennsylvania Greenhouses, as financial inventors and promoters representing the Pennsylvania life sciences industry, would provide useful and unique information. The Pennsylvania Greenhouses fund, promote, and develop a diverse array of life science organizations working in a variety of different fields. They can provide information concerning the Final Rules' effect outside of those in which the Plaintiffs practice. Further, the Pennsylvania Greenhouses can provide the unique perspectives of companies and organizations with missions, strategies, and resources that differ significantly from the Plaintiffs. Thus, while many of the Plaintiffs and the Pennsylvania Greenhouses other concerns about the Final Rules may overlap, the Pennsylvania Greenhouses will be able to provide useful information about the specific effects of the Final Rules across the life sciences industry, including information about Pennsylvania's investment, which is a model followed by other states that are also in early developmental stages of private-public economic development partnerships.

As discussed above, the Final Rules will adversely and irreparably affect early stage life sciences organizations' ability to adequately protect their inventions and to secure and maintain necessary funding for their research and development efforts. Further, as noted, the Final Rules will likely have a disparate impact on life sciences organizations because continuations practice is more prominent in the life sciences area than in others. These effects

have important implications for the public's access to innovations in life sciences and the benefits of such advancements. In particular, they may prevent the life sciences companies from developing the next generation of technological advances for the diseases and other health problems facing Pennsylvanians, citizens of this country, and mankind in general.

The Pennsylvania Greenhouses are filing their motion for leave to submit an *amicus* brief in advance of the anticipated summary judgment motions and briefing in order to bring to the Court's attention their interest in the outcome of these cases at an early stage and to allow sufficient time for the Court to consider its motion. To adhere to the current schedule in the *Tafas* case and in the *GSK* case, the Pennsylvania Greenhouses request that their *amicus* brief be due on December 27, 2007, the current due date for all such *amicus* briefs. If that schedule is modified or a different schedule is adopted in the *GSK* case, the Pennsylvania Greenhouses request that their brief be due on the same date as all other *amicus* briefs.

WHEREFORE, for the reasons stated herein and in its accompanying memorandum in support, the Pennsylvania Greenhouses respectfully request the Court to grant leave to file a collective *amicus* brief in support of the Plaintiffs' anticipated summary judgment motions.

Respectfully submitted,

/s/ _____
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December 21, 2007

CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of December 2007, I caused a copy of the foregoing Memorandum of *Amicus Curiae* The Pennsylvania Greenhouses in Support of Motion for Leave to File A Brief in Support 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:

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