

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

|                       |   |                     |
|-----------------------|---|---------------------|
| TRIANTAFYLLOS TAFAS,  | ) |                     |
|                       | ) |                     |
| Plaintiff,            | ) | 1:07cv846 (JCC/TRJ) |
|                       | ) |                     |
| v.                    | ) |                     |
|                       | ) |                     |
| JON W. DUDAS, et al., | ) |                     |
|                       | ) |                     |
| Defendants.           | ) |                     |
|                       |   |                     |

CONSOLIDATED WITH

|   |   |                      |
|---|---|----------------------|
| SMITHKLINE BEECHAM CORPORATION, et al., | ) |                      |
|   | ) |                      |
| Plaintiffs,                             | ) | 1:07cv1008 (JCC/TRJ) |
|   | ) |                      |
| v.                                      | ) |                      |
|   | ) |                      |
| JON W. DUDAS, et al.,                   | ) |                      |
|   | ) |                      |
| Defendants.                             | ) |                      |
|   |   |                      |

**BRIEF OF *AMICI CURIAE* IN SUPPORT OF PLAINTIFF'S MOTION  
FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

**I. Introduction and Summary**

HEXAS, LLC (“Hexas”), The Roskamp Institute and Tikvah Therapeutics, Inc. (“Tikvah”) (collectively “the *amici*”) respectfully submit this *amici curiae* brief in support of the pending motion of Plaintiffs (“GSK”) for a TRO and preliminary injunction against implementation of certain new rules promulgated by the United States Patent and Trademark Office (“the PTO”) which are presently set to go into effect on November 1, 2007. *See* Ex. A to GSK’s Memorandum of Law, 72 Fed. Reg. 46716 (“the New Rules”). More specifically, this

brief is being submitted to aid the Court's appreciation of the wide-ranging and significant harm to companies, industries, the investment in and advancement of technology, and the public interest, should implementation of these New Rules be permitted.

In short, the New Rules would limit the ability of inventors to fully secure the exclusive rights to their disclosed inventions by restricting, *inter alia*, the number of RCEs/continuation applications and patent claims available to them.

The justification advanced by the PTO is a reduced backlog of pending patent applications. (See Ex. A to GSK's Memorandum of Law, at 46752).

But, what of the costs?

At the ground level, the harm to technology companies will be substantial and wide-ranging, spanning virtually all major industries and companies of all sizes. This Court has already heard from GSK about the significant impact of the new Rules on its business. Although the *amici* may differ in size and many other respects from GSK, the detrimental impact of the New Rules on their respective businesses, however, will be equally profound. Indeed, the businesses of smaller, early-stage innovator companies, such as the *amici*, are literally built around their patent portfolios. These companies depend upon outside investment to fund their technology development and business operations -- and their investors bank on the expectation that the companies will be able to secure full and complete patent protection for the inventions and products so their investments can be recouped years later.

With the New Rules, and their substantive limitations on the abilities of inventors to attain full protection, come heightened risk and uncertainty in these investments.

Thus, in the short-term, the New Rules will negatively impact the abilities of the *amici*, and numerous other companies, to attract outside investment needed to fund business operations and development of their inventions into new products for society. Longer-term, the potential chill on investment in technology development could diminish the viability of early-stage companies, weaken important industries and retard the advancement of innovation -- results which are directly antithetical to the clear language, policies and goals of our Constitution (to “promote the Progress of Science”) and the Patent Act (35 U.S.C. et seq.). *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974).

In the end, innovators and industry will not be the only ones to suffer the consequences. The public-at-large will (unbeknownst to them) ultimately bear the burden of fewer new products that would help to improve their lives.

Accordingly, the *amici* fully agree with GSK’s positions on the legal merits and likelihood of success in this action and, particularly, that the PTO has clearly exceeded its rulemaking authority in promulgating the New Rules. The *amici* also certainly agree that the backlog of patent applications in the PTO is a problem which should be addressed.<sup>1</sup> The manner of addressing the backlog problem, however, should not be permitted to undercut the core tenets and policies upon which our Constitution was drafted and our patent system built -- at the expense of inventors, companies, investors and industries that foster those goals of scientific advancement for the benefit of us all.

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<sup>1</sup> Since the PTO is one of the few federal agencies which actually realizes a profit (based primarily on patent application filing fees), the *amici* respectfully suggest that the application backlog problem could be more effectively addressed by approaches that are in keeping with the policy objectives of the Constitution and patent laws including the hiring of additional patent examiners and/or increased investment in training and retention of new and existing examiners.

## **II. Interest of *Amici Curiae***

### **A. Hexas**

Hexas is an Alexandria, Virginia private company that develops and licenses technologies in the field of advanced materials and manufacturing. Hexas has a growing portfolio of patents based on its evolving proprietary system called Reflexive Materials Technologies (RMT™). RMT Technologies are the product of rich brew of science, math, long days, longer nights, and stale coffee for a lone inventor, Charles Owens, and the investors in the small company he founded. RMT has a wide range of structural/weight-carrying (e.g., aerospace, energy, automotive, medical, and construction industries) and non-structural (e.g., pharmaceutical, food, cosmetics, filtration, and agricultural industries) applications. For instance, the beaded RMT fibers are lightweight and reduce the amount of metals, plastics, and other materials required to make structural products. As a result, use of RMT™ composite materials and products can help reduce energy consumption, conserve natural resources and make autos, planes, and other vehicles more fuel efficient.

To ultimately achieve the promise of this innovative technology, however, many of these devices will require long-term continuing development and improvement along with continuing development of collateral and complementary systems. Hexas is highly dependent on its patent portfolio to attract the investment needed to fund the development of its technology. Currently, Hexas has a series of continuation applications pending before the PTO which will be directly impacted by the retroactivity of the New Rules. Hexas also hopes to file additional applications with the PTO for many more years based on continued development of RMT.

Continued development to realize the full promise of these technologies depends on the availability of patent incentives that will provide the inventor and his investors a chance to

earn a profit on the millions of dollars and thousands of days they have invested thus far, and the additional dollars and days they are willing to invest, in the development of RMT™ technologies. Absent such incentive and full patent protection, the value of this promising technology to society may never be realized.

### **B. The Roskamp Institute**

The Roskamp Institute is a Sarasota, Florida non-profit research institute dedicated to understanding the causes and finding cures for neuropsychiatric and neurodegenerative disorders and addictions, including Alzheimer's disease. The Institute was founded by Robert Roskamp, a successful entrepreneur and philanthropist, who came to understand first-hand the suffering associated with neuropsychiatric disorders when his brother was diagnosed with schizophrenia. Mr. Roskamp successfully recruited two world-renowned researchers, Drs. Michael Mullan and Fiona Crawford, members of a pioneering team of scientists who, in the early 1990s, made the ground breaking discovery that the onset of Alzheimer's was directly related to the accumulation of a protein called  $\beta$ -amyloid. The Institute currently has 45 scientists and 10 clinicians with eight active clinical trials in the field, and several additional trials planned in the near future. The Roskamp Institute also has active research programs directed to the discovery of novel and effective treatments for Traumatic Brain Injury and childhood disorders such as Tourettes Syndrome and Attention Deficit/Hyperactivity Disorder (ADHD).

The strength of the patent protection for these discoveries is vital to Roskamp's ability to make these treatments available to those who need them. Mr. Roskamp continues to provide significant support to the Institute through the Roskamp Foundation, but the Institute cannot do the extensive clinical work necessary to bring a drug to market all on its own. For the public to gain the benefit of treatments it discovers, The Roskamp Institute needs significant outside

investment, likely through venture capital funding or other institutional investment, and/or to partner with companies having the requisite resources. A strong patent portfolio is critical to attracting such investors and corporate partners.

The Roskamp Institute has 16 pending patent applications, several of which will be directly impacted by the retroactive limitations on the number of patent applications and patent claims available to inventors under the New Rules. The Roskamp Institute also hopes to file additional applications on the inventions resulting from its research efforts. The New Rules will negatively impact the Institute's ability to attract the institutional investment necessary to support further clinical work and place promising therapeutics into the hands of these growing patient populations, which are in dire need of novel treatments.

### **C. Tikvah**

Tikvah is an Atlanta, Georgia-based, developmental stage biopharmaceutical company focused on novel drug therapies for significant unmet needs in neurological and psychiatric indications. The company's product pipeline includes a therapeutic for children suffering from the devastating neurodegenerative disorder known as spinal muscular atrophy, as well as a novel therapeutic designed to ease sleep disturbances in totally blind individuals.

Tikvah is led by Dr. Harold Shlevin, the former CEO of Solvay Pharmaceuticals, a large public company. Although it was not an easy decision, Dr. Shlevin left Solvay for the challenge of creating a completely new company, from the ground up, to further the development of drugs he considered essential to, but absent from, the current marketplace. The company recently completed a \$10 million A round of venture capital financing on the promise of its technology and pending patent portfolio, but must raise considerably more funding to advance the clinical development of its drug candidates. This investment is driven by the expectations of investors in Tikvah's ability to obtain full and complete patent protection for its products.

Tikvah currently has 8 pending patent applications which will be directly impacted by the retroactive limitation on continuation and RCE applications. Tikvah also hopes to file additional applications on its current and future drug technologies. The company will be unable to make the further clinical progress necessary to bring these novel drug therapies to patients without adequate patent protection, which drives institutional investment. The New Rules will negatively impact that protection and hamper the company's progress toward new treatments for underserved clinical needs.

### **III. Harm to the *Amici* and the Public Interest**

#### **A. The U.S. Constitution and Policies of the Patent Laws**

The United States Government encourages research and development by granting patents to inventors. The basis for the patent system was provided back in 1787 by our Founding Fathers in the United States Constitution which specifically provides that “[t]he Congress shall have the power ... to promote the Progress of Science ... by securing for limited times to ... Inventors, the exclusive right to their ... Discoveries.” U.S. Const. Art. I, Sec. 8, d.8.

In order to exercise this power, Congress has passed laws which confirm that whoever invents or discovers any new and useful product may obtain a patent for each separate invention. 35 U.S.C. et seq. On this basis, the patent system has been designed to promote scientific progress by providing an incentive for investment and risk of large sums of money on research projects. The policy and purpose is clear and undisputed -- the authority of Congress is exercised in the hope that “[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-481, 94 S.Ct. 1879, 1885-1886, 40 L.Ed.2d

315 (1974). From the beginning, “the subject-matter provisions of the patent law[s] have been cast in broad terms to fulfill the constitutional and statutory goal of promoting ‘the Progress of Science and the useful Arts’ with all that means for the social and economic benefits envisioned by Jefferson.”<sup>2</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 315, 100 S.Ct. 2204, 2211, 65 L.Ed.2d 144 (1980).

The Federal judiciary has been ever mindful of the core principles underlying our patent system and the ultimate benefits to the public:

“When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.”

*Kewanee Oil*, at 481. Instead of fulfilling these Constitutional and statutory goals of promoting “the Progress of Science”, the New Rules disadvantage vital economic and social interests by retarding the benefits of patents to businesses and chilling investment in and advancement of technology innovation. New medical treatments for debilitating conditions, and advances in energy efficiency and other fields, are just some of the *amici*’s important technological advancements which will be impacted.

There must be a better way to reduce the PTO’s patent application backlog problem -- without contravening the language and policies of the Constitution and Patent Statute and/or threatening to deprive the public of the fruits of innovation.

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<sup>2</sup> “The Act embodied Jefferson’s philosophy that ‘ingenuity should receive a liberal encouragement.’ 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871)” *Id.* at 308-09; see also *Graham v. John Deere Co.*, 383 U.S. 1, 7-10, 86 S.Ct. 684, 688, 690, 15 L.Ed.2d 545 (1966).

#### IV. Conclusion

The federal judiciary has been ever mindful of the importance of the core policies underlying our patent system and economy. The *amici* respectfully urge the Court's continued vigilance in guarding their continued vitality, and the interests of our citizens, by granting of the requested injunction.

Dated: October 26, 2007

Respectfully submitted,

/s/

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing Brief of *Amici Curiae* in Support of Plaintiff's Motion for a Temporary Restraining Order and Preliminary Injunction was electronically filed in Case No. 1:07cv1008 (JCC/TRJ) using the CM/ECF system and that service was thereby accomplished on this 26<sup>th</sup> day of October, 2007, upon the following counsel:

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I further certify that a copy of the foregoing was also served by facsimile and United States Postal Service first-class mail this 26<sup>th</sup> day of October, 2007, upon the following counsel:

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