

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

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

CONSOLIDATED WITH

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

**MEMORANDUM IN SUPPORT OF MOTION OF *AMICUS CURIAE*
BIOTECHNOLOGY INDUSTRY ORGANIZATION FOR LEAVE TO FILE A BRIEF IN
SUPPORT OF PLAINTIFFS’ ANTICIPATED MOTIONS FOR SUMMARY
JUDGMENT**

The Biotechnology Industry Organization (“BIO”) submits this memorandum in support of its 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, BIO and its members have a substantial interest in this case, and, as a representative of the biotechnology industry, BIO can provide the Court with a unique 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 inventions. 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 biotechnology industry. This industry relies heavily on patent law and the current, established Patent and Trademark Office (“PTO”) rules of practice to obtain adequate coverage of its inventions and to attract financing for products that often take more than a decade to reach the market.

The changes in the PTO’s rules of practice have already caused changes to the patent strategies of many biotechnology organizations. When the Final Rules become effective on November 1, 2007, these effects will only increase and be amplified. BIO is deeply concerned about the irreversible loss of patent rights and the disincentives to innovation that the Final Rules will cause. BIO is uniquely positioned to provide the Court with information and perspective on the Final Rules’ impact on biotechnology organizations and products that the parties cannot, or may not have the incentive to, provide. BIO therefore should be granted leave to submit an *amicus curiae* brief in support of the plaintiffs at the summary judgment stage of this case.

BACKGROUND

BIO is the largest trade association representing the biotechnology industry. BIO was founded in 1993 to represent biotechnology companies at the local, state, federal, and international levels. As of December 2006, BIO’s membership consisted of more than 1,100 biotechnology companies, academic centers, state and local associations, and related enterprises. BIO’s members range from large Fortune 500 companies to the smallest start-ups and university

spin-offs. They are involved in researching and developing biotechnology products across a wide array of technology areas, including food and agriculture, healthcare, industrial, and environmental.

Biotechnology is one of the most research-intensive industries in the world. For example, in 2005, the U.S. biotechnology industry spent \$19.8 billion on research and development of more than 400 investigational drug products and vaccines. Modern crop science applies biotechnology to enhance productivity in corn, cotton, and soybean farming, and to reduce their environmental impact. Bioethanol made from crop wastes using enzymes developed by the biotechnology industry could meet a quarter of U.S. energy needs by 2025.

The vast majority of BIO's corporate members are development-stage companies that have yet to achieve profitability and that are years from bringing their technologies to market. Patents are vital to BIO's members. 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 biotechnology inventions. Sustaining the necessary level of financing and partnering depends on the ability to develop comprehensive patent protection for investigational biotechnology products. Furthermore, continuations practice is more prominent with respect to biotechnology patents than those in other technology areas, such as electronic and mechanical patents. Thus, the Final Rules are likely to have a disparate impact on BIO's members.

GlaxoSmithKline, which is a large multinational corporation that primarily researches and develops pharmaceuticals and other healthcare products, is a member of BIO. However, as described above, BIO represents a diverse array of biotechnology organizations of all sizes and working in all fields of biotechnology. Further, BIO has no stake in the GSK Plaintiffs, any of

the other parties to this litigation, or the result of this case other than its interest in avoiding changes to the patent laws and rules that will irreparably damage the biotechnology industry, BIO members, and the public.

ARGUMENT

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).

BIO's *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 BIO, as a representative of the biotechnology industry, could provide useful information. BIO represents a diverse array of biotechnology organizations working in a variety of different fields. BIO can provide information concerning the Final Rules' effect on technologies outside of those in which the plaintiffs practice. Further, BIO 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 BIO members' concerns about the Final Rules may

overlap, BIO will be able to provide useful information about the specific effects of the Final Rules across the biotechnology industry, including its members who are in the developmental stage. As discussed above, the Final Rule will adversely and irreparably affect biotechnology 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 biotechnology organizations because continuations practice is more prominent in the biotechnology area than in others. These effects have important implications for the public's access to innovations in biotechnology and the benefits of such advancements. In particular, they may prevent the biotechnology companies from developing the next generation of agricultural advances or drugs, treatments, and therapies for the diseases and problems facing mankind.

BIO is filing its motion for leave to submit an *amicus* brief well in advance of the anticipated summary judgment motions and briefing in order to bring to the Court's attention its members' interest in the outcome of these cases at an early stage and to allow sufficient time for the Court to consider its motion. If the current schedule in the *Tafas* case is adopted in the GSK case, BIO requests that its *amicus* brief be due on November 14, 2007, one week after the current due date for Mr. *Tafas*'s motion for summary judgment. If the *Tafas* schedule is modified or a different schedule is adopted in the GSK case, BIO requests that its brief be due one week after the GSK Plaintiffs file their summary judgment motion.

Counsel for the GSK Plaintiffs and Mr. *Tafas* have consented to the filing of this motion. The defendants take no position on this motion. However, all parties agree that the motion should be decided without oral argument.

CONCLUSION

For all of the foregoing reasons, BIO respectfully requests that the Court grant it leave to file an *amicus* brief in support of the plaintiffs' anticipated summary judgment motions.

Respectfully submitted,

ARNOLD & PORTER LLP

By: _____/s/
Randall K. Miller
VA Bar #70672
Counsel for Amicus Curiae
Biotechnology Industry Organization
1600 Tysons Boulevard
Suite 900
McLean, VA 22102
Telephone: (703) 720-7030
Facsimile: (703) 720-7399
Randall.Miller@aporter.com

Of Counsel for Amicus Curiae
Biotechnology Industry Organization:

Ronald A. Schechter
David R. Marsh
Matthew M. Shultz
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
Telephone: (202) 942-5000
Facsimile: (202) 942-5999

ATTORNEYS FOR *AMICUS CURIAE*
BIOTECHNOLOGY INDUSTRY
ORGANIZATION

October 29, 2007

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of October 2007, I caused a copy of the foregoing Memorandum in Support of Motion of *Amicus Curiae* Biotechnology Industry Organization for Leave to File a Brief in Support of the Plaintiffs' Motions for Summary Judgment was 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 Ave.
Alexandria, VA 22314
Email: lauren.wetzler@usdoj.gov

Counsel for Defendants

Thomas J. O'Brien
Morgan, Lewis & Bockius
1111 Pennsylvania Ave., 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 Ave., NW
Washington, DC 20004

Counsel for Putative Amicus Pharmaceutical Research and Manufacturers of America

/s/

Randall K. Miller
VA Bar #70672
*Counsel for Amicus Curiae Biotechnology Industry
Organization*
1600 Tysons Boulevard
Suite 900
McLean, VA 22102
Telephone: (703) 720-7030
Facsimile: (703) 720-7399
Randall.Miller@aporter.com