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# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA

(Alexandria Division)

TRIANTAFYLLOS TAFAS,	)	
Plaintiff,	)	
V.	)	Civil Action No. 1:07cv846 (JCC/TRJ)
JON W. DUDAS, et al.	)	
Defendants.	) ) )	
	CONSOLI	DATED WITH
SMITHKLINE BEECHAM CORPORATION, et al.	)	
Plaintiffs,	j	
V.	)	Civil Action No. 1:07cv1008 (JCC/TRJ)
JON W. DUDAS, et al.	)	
Defendants.	) ) )	

# MEMORANDUM IN SUPPORT OF MOTION OF CROPLIFE AMERICA FOR LEAVE TO FILE AN AMICUS CURIAE BRIEF

Pursuant to the Court's December 18, 2007 Order, CropLife America (CLA) has moved for leave to file a brief as *amicus curiae* on December 27, 2007, in support of Plaintiffs in this case challenging newly issued Patent and Trademark Office (PTO) rules governing important aspects of patent protection practice. Plaintiffs do not oppose CLA's Motion, while Defendants take no position with regard to the Motion.

CropLife submits that it has unique and useful information to provide to the court in its brief that will assist the court in resolving the important issues before it.

#### FACTUAL BACKGROUND

On August 21, 2007, the PTO published the Final Rules that are at issue in this case. The PTO's new rulemaking upends the well-established current patent scheme and, consequently, an inventor's ability to protect its trade secrets and patent applications through continuing applications, additional claims, and requests for continued examination (RCE). Specifically, Final Rules 78 and 114 allow, as a matter of right, a patent applicant to file two continuation applications, as well as a single RCE, after the filing of its initial application. *Tafas v. Dudas*, 511 F. Supp.2d 652, 657 (E.D. Va. 2007). In order to prosecute a third continuing application, or a second RCE, an applicant must submit a "petition and showing" explaining why the amendment, or the bases for the amendment, could not have been submitted with previously filed applications. *Id.* These Rules apply to all initial and continuing applications filed on or after November 1, 2007. *Id.* As a result, the provisions are to be applied retroactively to pending initial applications that are the subject of a continuing application. Pls.' Br. 10-11.

Because of these Rules, if GlaxoSmithKline cannot satisfy the "could not have been submitted" showing for a particular continuing application, it will lose the benefit of priority it was otherwise entitled to under the old Rules. Pls.' Br. 9. With respect to the submission of claims, Final Rule 75 limits an applicant to a total of five independent claims and twenty-five total claims without providing any further information about those claims. *Tafas*, 511 F.Supp.2d at 658. In order to exceed that limitation, Rule 75 requires an applicant to submit an "examination support document" (ESD) containing information

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<sup>&</sup>lt;sup>1</sup> The Final Rules were entitled "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications." 72 Fed. Reg. 46716-46843 (Aug. 21, 2007). The Final Rules were to be codified at 37 C.F.R. pt. 1 with an effective date of November 1, 2007.

about the claims that may assist the examiner in determining the patentability of the claimed inventions. *Id.* This Rule applies to all application filed on or after November 1, 2007, thus, the Rule is to be applied retroactively. *Id.* 

In arguing against the requested temporary restraining order, the PTO stated that there were no property rights implications in its new rules. 72 Fed. Reg. 46,716, 46,834 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1). Specifically, the PTO argued that companies do not have a vested property right in their patent applications. Defs.' Br. 33 (citing *Marsh v. Nichols, Sheperd & Co.*, 128 U.S. 605, 612 (1888)). Based upon this assertion, the PTO argued that there could be no retroactivity finding. Defs.' Br. 33.

#### INTERESTS OF CROPLIFE AMERICA

The members of CropLife America (CLA) are the world's leaders in the development of improved crop protection and bioengineered plants. They invest many millions of dollars a year to develop new and better sources of food, fiber, and fuel for America and the world. America's leadership in this technological innovation is made possible only by the strong legal protections provided by our nation's patent system, through which CLA's member companies are able to recoup the enormous cost of developing these inventions and processes by obtaining, in return, a limited exclusive right to market these products.

CLA was organized in 1933 as a national, non-profit trade organization representing the major manufacturers, formulators, and distributors of crop protection and pest control products. Headquartered in Washington, D.C., CLA's member companies produce, sell, and distribute most of the active compounds used in crop protection products registered for use in the United States. CLA's members are responsible for

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obtaining EPA's registration of their products, which cannot be sold unless registered. *See* Federal Insecticide, Fungicide, and Rodenticide Act § 3, 7 U.S.C. § 136a (West 2007). CLA represents its members' interests by monitoring federal agency regulations and agency actions and related litigation to identify issues of concern to the crop protection and pest control industry, and participating in lawsuits when the interests of its members are at stake.

The immense benefits that crop protection and biotechnology have already delivered to growers and will deliver in the future do not come without cost. The process of researching promising chemical formulations and genetic traits and commercializing the resulting products is expensive and time-consuming. For example, Monsanto Company invested decades and hundreds of millions of dollars in developing a trait for tolerance to herbicides that could be used in crop plants, and Pioneer Hi-Bred International, Inc. and Syngenta (along with its predecessors) each invested comparable time and sums in developing crop plant traits for insect resistance. Although many of these investments have proven valuable in hindsight, for every innovation that is commercialized, biotechnology companies must investigate numerous possibilities that do not yield significant economic return.

To encourage such companies to risk "often enormous costs in terms of time, research, and development," *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974), the Patent Clause of the U.S. Constitution gives Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. The laws Congress has passed pursuant to the Patent Clause, *see*, *e.g.*, 35

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U.S.C. §§ 101-105, apply to protect not only those who develop novel inanimate objects, but also those who invent novel living organisms, including, among other things, bioengineered bacteria and plant breeds. See Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980) ("[T]he relevant distinction [is] not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."); see also J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).

#### **ARGUMENT**

The decision whether to allow a non-party to participate as *amicus curiae* is within the court's discretion. Tafas, 511 F. Supp.2d at 659; Cobell v. Norton, 246 F. Supp.2d 59, 62 (D.D.C. 2003). As this Court has recognized, amicus are "allowed at the trial level where they provide helpful analysis of the law" or "they have a special interest in the subject matter of the suit . . . . " Tafas, 511 F. Supp.2d at 659. "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." Ryan v. Commodies Futures Trading Comm'n, 125 F.3d 1062 (7th Cir. 1997). As discussed below, CLA meets this standard and the court should therefore grant its motion for leave to file an amicus brief in this case.

CLA's brief will address the property rights implications of the PTOs new rules, including the potential that the PTO's new rules will result in unconstitutional takings of private property in violation of the Fifth Amendment, and the appropriate remedy for the taking of patent rights. CLA's brief will also discuss the legal implications of PTO's failure to adequately consider the takings implications of its new rules. Lastly, CLA's brief will examine the historical context for the recognition of patent rights as a form of

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property rights, and explain why it was important to the Framers of our legal system that inventors receive strong patent protection to reward their hard work and innovation.

As a representative of the plant science and crop protection industry, CLA can provide useful information about these issues. CLA's member companies and organizations have different missions, strategies, and resources from the Plaintiffs, and therefore the effect of the new PTO rules on these companies and organizations will be different from Plaintiffs' experiences. CLA can also present the court with useful information on the property rights implications of the PTO's new rules, beyond that presented by the parties.

Where Plaintiffs and CLA's concerns about the new PTO rules might coincide, CLA can supply the court with information on the effects of the new PTO rules on the plant science and crop protection industry. The new PTO rules threaten to adversely and irreparably affect CLA members' ability to protect their intellectual property and investment in research and development. Because continuing applications are prevalent and necessary in the plant science and crop protection industry, the new PTO rules will have a greater impact in the crop protection field. As CLA's *amicus* brief will explain, the new rules do not reward incremental innovation and will impair CLA members' ability to develop the next generation of plant science advances or formulate new strains of plants to meet environmental and human health need.

Accordingly, CLA meets the standard required for leave to file as amicus curiae in this case, and CLA can provide the court with new and unique information that is timely and useful, and not available from the parties themselves.

## **CONCLUSION**

For the foregoing reasons, CLA respectfully asks this Court to grant its Motion for Leave to File a Brief as amicus curiae in support of Plaintiffs.

Respectfully submitted,

December 20, 2007

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#### **CERTIFICATE OF SERVICE**

I hereby certify that on the 20th Day of December, 2007, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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\_/s/\_\_\_

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