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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.)
CONSO	LIDATED 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 MONSANTO COMPANY FOR LEAVE TO FILE A BRIEF IN SUPPORT OF PLAINTIFFS' ANTICIPATED MOTIONS FOR SUMMARY JUDGMENT

Monsanto Company ("Monsanto") 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, Monsanto has a substantial interest in these cases and can provide the Court with a unique perspective on the issues presented by these matters.

INTRODUCTION

Monsanto, along with its subsidiaries, is a leading global provider of agricultural products for farmers. The seeds, biotechnology trait products, and herbicides that Monsanto researches, develops, and brings to market provide farmers with solutions that improve productivity, reduce the costs of farming, produce better feed for animals, and produce better foods for consumers. Monsanto's Seeds and Genomics segment produces leading seed brands, including *DEKALB*, *Asgrow*, *D&PL*, *Deltapine*, and *Seminis*, and develops biotechnology traits that assist farmers in controlling insects and weeds. Monsanto also provides other seed companies with genetic material and biotechnology traits for their seed brands. Through its Agricultural Productivity segment, Monsanto manufactures herbicides, including *Roundup* brand herbicides, provides lawn-and-garden herbicide products for the residential market, and provides animal agricultural products focused on improving dairy cow productivity. Monsanto has no stake in any of the plaintiffs in this case. Monsanto seeks leave to participate as an *amicus* based upon its interest in avoiding changes to the patent rules—particularly certain rules changes described below—that will irreparably harm its business, the biotechnology industry generally, and the public.

Monsanto spends over \$2 million per day in research and development to support and improve its businesses. Patents are a critical component of Monsanto's research and development activities and a significant factor in Monsanto's willingness to devote such substantial resources to these activities. 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). If the Final Rules go into effect, Monsanto is deeply concerned about the adverse and irreparable effects that may result from the operation of sections 75 and 265 of the Final Rules, which limit applicants to five independent claims and twenty-five total claims unless the applicant files an "examination support document" ("ESD"), hereinafter referred to as the "5/25 Rule."

Particularly relevant here, within Monsanto's herbicide business, it has several patents on new formulations and manufacturing processes, including catalysts that are used in various intermediate steps in the production of herbicides. Biological and chemical products such as these typically are developed in progressive stages. Once the initial discovery is made, a patent application is filed that claims the new invention. Additional research may lead to a better understanding of the invention or of its important properties. New independent or dependent claims may thus be necessary to more clearly and accurately define the invention and to fully protect the entire scope of the invention. This is particularly important with respect to biological inventions because they are inherently difficult to define.

Monsanto is uniquely positioned to provide the Court with information and perspective on the effects of the Final Rules, and the 5/25 Rule in particular, on inventions developed in this way that the other parties cannot, or may not have the incentive to, provide. Monsanto therefore should be granted leave to submit an *amicus curiae* brief in support of the plaintiffs at the summary judgment stage of this case.

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).

Monsanto's *amicus* brief would address the balance of hardships and the public interest prongs of the plaintiffs' requests for injunctions permanently enjoining the implementation of the Final Rules. In particular, as noted, Monsanto will address the adverse and irreparable effects of the 5/25 Rule, not only on patent applications and patent prosecution, but also in subsequent proceedings, such as litigation, related to affected patents. The 5/25 Rule, alone and in combination with other provisions of the Final Rules, will result in the forfeiture of patent rights, particularly for those inventions that undergo the progressive research and development process described above. As a result of the forfeited patent rights, patent holders will be less able to defend their patents in subsequent litigation than under the current PTO rules. In practice, an ESD is not a viable option because of the exorbitant expense of preparing one, the risk of committing to an adverse claim construction without full knowledge of the technology's potential market, and the risk that representations made in the ESD will spawn claims of inequitable conduct in subsequent litigation.

Many of Monsanto's inventions are developed through generations of progressive development, including the catalysts mentioned above, and will be adversely affected in the ways discussed. While plaintiffs have generally challenged the 5/25 Rule, Monsanto will be able to provide a unique perspective on specific harms and implications of the 5/25 Rule, which the parties may not be able to do. Moreover, many of the inventions that will be affected are protectable as trade secrets, and patent applicants may opt for this type of intellectual property protection instead of the less robust patent protections that will result if the Final Rules are implemented. If this were to occur, the public welfare would suffer as a result of the lack of public disclosure of these inventions.

Monsanto is aware that Defendants' Motion for Issuance of Proposed Briefing Schedule in Lieu of a Standard Initial Scheduling Order, Dkt. No. 60, is currently pending and that the hearing on this motion has been continued until November 27, 2007, Minute Entry, Dkt. No. 68. If Monsanto's motion for leave is granted, it requests that its *amicus* brief be due one week after plaintiffs' motions for summary judgment are due. Monsanto requests this time after the filing of the plaintiffs' summary judgment motions so that it has the opportunity to review the motions and to tailor its brief in light of the plaintiffs' arguments. This will help ensure that Monsanto engages the plaintiffs' arguments in a way that will be most beneficial to the Court's consideration of the issues. Although Monsanto believes that one week between the filing of the plaintiffs' summary judgment motions and the filing of amicus briefs in support of plaintiffs' motions is appropriate, it will abide by and not object to the due date for amicus briefs in support of the plaintiffs' summary judgment motions as provided in the schedule that will be entered by the Court.

Counsel for the GSK Plaintiffs has consented to the filing of this motion. Counsel for Mr. Tafas has consented to the filing of this motion, except, at this juncture, he takes no position with respect to Monsanto's request for a due date one week after the due date for plaintiffs'

motions for summary judgment. 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, Monsanto respectfully requests that the Court grant it leave to file an amicus brief in support of the plaintiffs' anticipated summary judgment motions in accordance with the scheduling order to be entered by the Court.

Respectfully submitted,

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November 26, 2007

CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of November 2007, I caused a copy of the foregoing Memorandum in Support of Motion of Amicus Curiae Monsanto Company for Leave to File a Brief in Support of the 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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