



April 9, 2008

COURT STRIKES DOWN U.S. PATENT OFFICE REGULATIONS *(SmithKline Beecham Corp. v. PTO)*

Last week, the U.S. District Court for the Eastern District of Virginia struck down two sets of new regulations issued by the U.S. Patent and Trademark Office (PTO) that would (1) severely restrict the number of "continuation" applications a company may file based on its original patent application, and (2) limit the number of claims that an applicant could present as a matter of right. The court found that the rules were substantive rather than procedural in nature, and thus, beyond PTO's statutory authority.

In *SmithKline Beecham Corp. v. PTO*, the PTO initially issued the rules that would limit an inventor to no more than two "continuation" applications based on its original filing, that is, additional information and data supporting the original patent application. The new rules, which were to become effective on November 1, 2007, were preliminarily enjoined on October 31, 2007 by U.S. District Court Judge James Cacheris. The court held the rules in abeyance while it considered the motions for summary judgment filed by both sides to the case.

In its brief filed on December 27, 2007, WLF explained how patent applications are a valuable asset, even though the patent has not been granted. Indeed, pending applications are routinely made available for licensing long before any patents issue. Accordingly, the PTO failed to conduct the required analysis under Executive Order 12630 for new rules that affect property rights; instead, it summarily concluded that the new rule "will not effect a taking of private property." Clearly, the impact of the rules was substantive rather than procedural in nature. Numerous industry trade groups, such as Pharma and the Biotechnology Industry Organization (BIO), also filed briefs opposing the PTO rules because they would seriously harm the rights of inventors and patent applicants. The PTO has 60 days to decide whether it will appeal the decision.

WLF's brief was filed with the *pro bono* assistance of Alan Charles Raul, David L. Fitzgerald, Ann M. Mace, and Kevin H. Henry of the Washington, D.C. law firm of Sidley Austin LLP.

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For further information, contact WLF Senior Executive Counsel Paul Kamenar at 202-588-0302. A copy of WLF's brief is available on its website at www.wlf.org.