

# Planned changes to patent procedures on hold for now

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We can all stop screaming now — at least for the time being. If you've followed the past few Intellectual Property articles in this column, you'll recall that we advocated screaming bloody murder over the new rules that the United States Patent & Trademark Office (PTO) intended to take effect on Nov. 1. A beautiful thing (in this author's opinion) happened, however, on the eve of that destructive day. The Court of Appeals for the Federal Circuit (CAFC), junior sibling to the U.S. Supreme Court, issued a preliminary injunction temporarily restraining the PTO from implementing their new rules.

GlaxoSmithKline (GSK), the second largest pharmaceutical company in the world, and another party, went before the CAFC in earnest seeking this result. GSK argued, in part, that they would be irreparably harmed if, and as soon as, the new rules went into effect. GSK currently has about 2,000 pending patent applications and argued that they would have to begin making strategic decisions, which will permanently affect their rights under patent law, whether or not the rules are eventually invalidated. In addition, GSK claimed it would suffer from great uncertainty about how to comply with the new rules, incur significant cost in



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creating required support documentation, and would lose a substantial amount of investment capital because it will be too late to save patent rights covering medical inventions that cannot proceed to market without strong protection. As such, potentially helpful drugs will be lost to both GSK and the public.

Here is some background. Remember, the patent system is designed to encourage companies like GSK to engage in the research and development of new drugs by providing them with the legal protection that enables them to recover the significant costs that accompany development and regulatory approval of new drugs.

Under the old and new rules, an inventor files a patent application with the PTO. The first (parent) application contains a specification, and one or more claims that identify the scope of the legal protection for the invention. Then, a patent examiner determines whether the claimed invention meets the legal requirements for getting a patent. If not, the examiner issues an Office Action that contains the grounds for rejection. An applicant may then argue against the rejection or present evidence to show why the invention is patentable. The examiner must respond by either allowing or rejecting the claims. Upon receiving a final rejection, an applicant can only: (1) appeal; (2) file a request for continued

examination (RCE); (3) file a continuation application; (4) file an after final amendment; or (5) drop it all.

On Jan. 3, 2006, the PTO proposed changes to its rules that would limit the number of continuation applications, RCEs, and claims. The PTO justified the changes on the ground that the growing workload had crippled the PTO's ability to examine new applications.

Under the old system, an applicant could file an unlimited number of continuations and RCEs, and submit an unlimited number of claims. Under the new rules, only two continuations, a single RCE, and a total of five independent claims and 25 total claims in each application would be allowed (without undue hoop-jumping).

In addition to suffering irreparable harm, GSK argued that the PTO is only empowered under the law to make rules about procedures, not substantive rights; that the new rules will not provide a significant gain in PTO efficiency or backlog reduction; and that by not preserving the *status quo*, the possibility of potential immediate harm to the public exists; i.e., many companies rely upon the stable, reliable protection afforded by the current patent system in determining whether

it is cost effective to abandon their trade secret protection by pursuing a patent. Implementation of the new rules would change those companies' calculus and immediately decreases their ability to pursue costly new innovations.

The Court determined that allowing the implementation of rules that, in due course, may or may not remain in effect, is likely to cause much greater uncertainty and squelching of innovation than a preliminary injunction (now) giving the Court time to consider the validity of the rules before they go into effect. Thus the Court decided that the public interest was most served by continuing the *status quo*.

Stay tuned; I'll let you know when its time to scream again.

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