

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

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**SMITHKLINE BEECHAM  
CORPORATION,  
d/b/a GLAXOSMITHKLINE,  
SMITHKLINE BEECHAM PLC, and  
GLAXO GROUP LIMITED, d/b/a  
GLAXOSMITHKLINE,**

**Plaintiffs,**

v.

**JON W. DUDAS, in his official capacity  
as Under Secretary of Commerce  
for Intellectual Property and Director  
of the United States Patent and  
Trademark Office, and**

**UNITED STATES PATENT AND  
TRADEMARK OFFICE,**

**Defendants.**

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**Civil Action No. 1:07cv1008**

**PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND  
PRELIMINARY INJUNCTION**

Pursuant to Rule 65, plaintiffs, SmithKline Beecham plc, SmithKline Beecham Corporation d/b/a GlaxoSmithKline, and Glaxo Group, Limited d/b/a GlaxoSmithKline (collectively referred to as "GSK"), move the Court for an order enjoining the Director and the PTO from implementing the PTO's "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 Fed. Reg. 46716, 46716-46843 (Aug. 21, 2007) (to be codified at 37

C.F.R. pt. 1) (“the Final Rules”) pending this Court’s ruling on the merits on the following grounds:

1. Plaintiff GSK respectfully requests that the Court preliminarily and permanently enjoin the Director and PTO from implementing the Final Rules on November 1, 2007. If not enjoined, the Final Rules will amend various sections of the PTO’s Rules of Practice and Procedure, which are set forth in Title 37 of the Code of Federal Regulations, and, in many instances, will apply retroactively. Most relevant, the Final Rules restrict a patent applicant’s ability to file continuing applications; restrict an applicant’s ability to file requests for continued examination; and restrict the number of claims an applicant may present in its application. If the PTO is allowed to implement the Final Rules on November 1, 2007, then GSK, and other innovator companies like it, will be substantially and irreparably harmed.

2. As demonstrated more fully in the attached memorandum in support, GSK is likely to succeed on the merits. The Final Rules are *ultra vires* because the Final Rules are substantive in nature and the PTO lacks any authority to issue substantive rules. The Final Rules also improperly restrict the number of continuing applications, requests for continued examination, and claims an applicant may file in contravention of 35 U.S.C. §§ 2, 111, 112, 120, 121, 132, and 365. Finally, provisions of the Final Rules should be enjoined as vague because they do not put GSK on sufficient notice as to how to comply.

3. GSK will be irreparably harmed if the Final Rules are implemented and later stricken. Once implemented, GSK will immediately be required to make business and patent strategy decisions that will be irreversible. GSK will be adversely affected because GSK relies on strong patent protection, including continuations and breadth of claims, to recoup the billions

it invests annually in researching and developing medicines to treat serious and life-threatening illnesses.

4. The balance of hardships tips decidedly in GSK's favor. The potential harm to GSK is unquestionable, significant, and irreversible. Conversely, if the PTO were prevented from implementing the Final Rules until an ultimate decision on the merits, then the PTO would merely be operating under the status quo.

5. Finally, the public interest favors enjoining the Defendants from implementing the Final Rules. It is in the public interest to insure that changes to the patent system do not cause a disincentive to GSK to bring more lifesaving drugs to market, or cause GSK to drop a research program on a lifesaving drug because of a loss of patent rights.

The grounds and reasons for granting this relief are stated with more particularity in the accompanying brief, declarations, and exhibits.

Date: October 15, 2007

Respectfully submitted,

/s/

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and Glaxo Group Limited d/b/a  
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**CERTIFICATE OF SERVICE**

I hereby certify that a true copy of the foregoing pleading was filed electronically this 15th day of October 2007 using the CM/ECF system, which will send notification by electronic means to the following counsel of record:

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