

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

(Alexandria Division)

**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.

Civil Action No. 1:07cv1008

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

Having considered Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction brought pursuant to Fed. R. Civ. P. 65, seeking entry of a Temporary Restraining Order and Preliminary Injunction against Defendant 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 Defendant United States Patent and Trademark Office ("PTO") (collectively, "Defendants") enjoining the implementation of 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, 46716-843 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) (“the Final Rules”) pending this Court’s ruling on the merits, the memorandum in support thereof, the declaration and exhibits in support thereof, and all other submissions and arguments concerning the motion, and the entire record before this Court, this Court finds:

1. Plaintiffs are likely to succeed on the merits of their action showing that:

A. The Final Rules’ various restrictions on patent application rights are all *ultra vires* because the PTO lacks the authority to issue substantive rules in this area. Accordingly, the Director and PTO have acted in a manner “not in accordance with law,” and “in excess of statutory jurisdiction and authority,” 5 U.S.C. § 706, running afoul of 35 U.S.C. §§ 2, 120, 131, 132, and 365.

B. The Final Rules’ restrictions on the number of continuing applications that may be filed are contrary to 35 U.S.C. § 120 and, therefore, the Director and the PTO have acted in a manner “not in accordance with law,” and “in excess of statutory jurisdiction and authority,” 5 U.S.C. § 706, running afoul of 35 U.S.C. §§ 2, 120.

C. The Final Rules retroactively change the legal consequences of already-filed applications and patent prosecution strategies and, in promulgating such rules, the Director and the PTO have acted in a manner “not in accordance with law” and “in excess of statutory jurisdiction and authority,” 5 U.S.C. § 706, under the Supreme Court’s retroactivity law, which severely restricts agency powers to engage in rulemaking of that nature.

D. The Final Rules' restrictions on the number of claims an applicant may submit are contrary to the Patent Act and, in promulgating such rules, the Director and the PTO have acted in a manner "not in accordance with law" and "in excess of statutory jurisdiction and authority," 5 U.S.C. § 706, running afoul of 35 U.S.C. §§ 2, 111, 112, and 131.

E. By restricting requests for continued examination, the Director and the PTO have acted in a manner "not in accordance with law" and "in excess of statutory jurisdiction and authority," 5 U.S.C. § 706, running afoul of 35 U.S.C. §§ 2 and 132.

F. The Final Rules are vague and do not put GSK on sufficient notice as to how to comply and, by issuing final regulations that are vague and indefinite under *United States v. Lanier*, 520 U.S. 259, 265 (1997), the Director and PTO have acted in a manner "contrary to constitutional right, power, privilege, or immunity," 5 U.S.C. § 706, violating the Fifth Amendment of the Constitution.

2. Plaintiffs will be irreparably harmed if the Director and the PTO are permitted to implement the Final Rules during the pendency of this action.

3. The harm to the Plaintiffs if the Director and the PTO are not enjoined substantially outweighs the harm to the Director and the PTO of maintaining the status quo during the pendency of the action.

4. The public interest in maintaining the status quo and ensuring that the Patent Act promotes innovation outweighs any minimal benefit to be gained by implementation of the Final Rules.

IT IS on this _____ day of _____, 2007, hereby

ORDERED as follows:

1. Defendants are preliminarily enjoined from implementing the Final Rules titled “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).

2. Defendants are preliminarily enjoined from issuing new regulations restricting the number of continuing applications, the number of requests for continued examination, and the number of claims that may be filed with the PTO that are deficient in any of the ways described above.

3. The following schedule is established for the briefing of the issues on summary judgment and a hearing on said issues:

A. Plaintiffs will file their motion for summary judgment on Monday, October 29, 2007.

B. Defendants will submit any cross-motion for summary judgment, as well as its opposition to Plaintiffs’ summary judgment motion on or before Tuesday, November 20, 2007.

C. Plaintiffs will file their reply in support of their motion for summary judgment, as well as its opposition to Defendants’ cross-motion for summary judgment on or before Thursday, December 6, 2007.

D. Defendants will file their reply in support of their cross-motion for summary judgment on or before Monday, December 17, 2007.

5. This Order shall expire upon the entry of a final judgment in this matter, unless otherwise ordered by the Court.

The Honorable Claude M. Hilton, U.S.D.J.