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USPTO Enjoined from Enforcing New Rules

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Eastern District of Virginia Enjoins USPTO from Implementing Revised Final Patent Rules

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On October 31, 2007, Judge James C. Cacheris of the Eastern District of Virginia enjoined the United States Patent and Trademark Office from implementing the revised Final Patent Rules ("Final Rules"), which were set to take effect today.

The Order issued following a complaint and request for temporary restraining order and preliminary injunction filed by GlaxoSmithKline ("GSK") early last month. GSK filed its complaint after the Patent Office released the Final Rules on August 21, 2007. GSK sought to enjoin implementation of the Final Rules pending the outcome of its case. The American Intellectual Property Law Association and several corporations, including Elan Pharmaceuticals and Hexas, LLP, filed amicus briefs supporting GSK's challenge.[1]

After ordering the injunction directly from the bench, Judge Cacheris issued a 39-page written opinion late yesterday. Applying the traditional four-factor test for preliminary injunctions, the Court considered (i) the likelihood of success on the merits; (ii) irreparable injury to GSK; (iii) the balance of hardships; and (iv) the public interest.

Likelihood of Success on the Merits

The Court noted at the outset that the Patent Office does not possess any substantive rule-making power and that GSK has raised a "colorable question" as to whether the Final Rules are "truly substantive." The Court also found that GSK raised "serious concerns" as to whether the Final Rules comport with the Patent Act. In particular, the Court considered GSK's concerns over the limitations on the number of continuing applications, requests for continued examinations (RCEs), and number of claims as well as retroactivity of the Rules and the requirements for examination support documents (ESDs).

With respect to limitations on the number of continuing applications, the Court found this limitation likely to run afoul of 35 U.S.C. § 120, which essentially prevents the Patent Office from setting such a limit notwithstanding the doctrine of prosecution laches. The Court was not persuaded by the Patent Office's argument that it would review petitions for a third continuing application on a "case-by-case" basis.

GSK argued similarly that Section 132 of the Patent Act prevents limitations on the number of RCEs filed. The Court did not find a likelihood of success on this issue as to either party because of the limited briefing.

On restricting the number of claims, the Patent Office provided evidence of improved administrative efficiencies, which supported the proposed limitation. Because it could not find a "clear error in judgment" by the Patent Office in establishing this limit, the Court found that GSK had not shown a likelihood of success on this issue.

Retroactivity is one of the most significant aspects of the Final Rules for it imposes an entirely new set of rules against standards that practitioners and patent holders have been relying on for decades. The Court recognized GSK's concern that in seeking patent protection for a particular technology, it surrenders property

rights in that technology as a trade secret. Retroactively applying the Final Rules "alters the bargain on which inventors like GSK rely in making their decision to surrender their rights." The potential effect on this "bargain" weighed heavily in the Court's determination that GSK would likely succeed on this issue.

In addition to the four changes discussed above, the Court also agreed with GSK that the revised ESD requirements are so vague that a reasonably prudent person may not be able to comply with them, tipping the likelihood of success scale in favor of GSK on this issue as well.

Irreparable Harm

In finding irreparable harm, the Court focused on the costs associated with the uncertainty of the Final Rules, which would provide a disincentive to further patent application filings and stifle research on new pharmaceutical products. The Court also expressed concern about the sufficiency of guards against lost patent protection as well as GSK's inability to recover its losses if the Rules are ultimately determined invalid.

Balance of Hardships

The Court acknowledged the hardship on the Patent Office caused by the resources expended on examiner training and computer updating required to implement the new rules. Nonetheless, it held that the uncertainty regarding enforceability of the Final Rules, coupled with the loss of investment that GSK would suffer if the Rules were to issue, outweighed any potential hardship on the Patent Office.

Public Interest

GSK again focused on stability, noting that innovation is encouraged "when patent holders and applicants have certainty about how their patents will be treated." The Court noted that allowing rules to issue now, even though they may not remain in effect, would serve to heighten the uncertainty and discourage innovation, to the detriment of society as a whole. The preliminary injunction preserves the status quo until the enforceability of the Final Rules is ultimately determined.

The GSK case underscores the mixed response received by many of the Patent Office's most recent reform efforts. Many patent applicants share GSK's concerns that such reforms inadequately address several key issues including patent portfolio management, innovation, and maintaining the delicate balance between trade secrets and patent protection. While providing only interim relief, the GSK injunction sends a strong message that patent reform is critically important. Judge Cacheris's opinion highlights many of the key arguments and problems with the Final Rules, and should play a central role in shaping further reform.

Footnotes:

[1] Although the amicus briefs raised additional questions regarding the Patent Office's ability to implement the Final Rules, the Court did not entertain any legal issues or arguments from these briefs not raised by the parties themselves.