

## **No Train Wreck, For Now What's Next for the "New Rules" After the Glaxo Injunction?**

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On October 31, 2007, in response to a motion filed by GlaxoSmithKline (Glaxo), Judge Cacheris of the Eastern District of Virginia enjoined the USPTO from implementing the final rules package as published on August 21, 2007 and set to take effect November 1<sup>st</sup> (the "New Rules"). In addition to its 39-page opinion, the Court issued a two-page order that specifically blocks the New Rules from taking effect until a final judgment has been entered in the Glaxo lawsuit.

### **Preliminary Injunction Findings**

The Court applied the traditional four-factor test for preliminary injunctions considering (i) the likelihood of success on the merits; (ii) irreparable injury to Glaxo; (iii) the balance of hardships; and (iv) the public interest. The Court found that each of the factors favored a preliminary injunction on at least some of the arguments made by Glaxo, including that the New Rules were beyond the statutory authority of the USPTO, impermissibly retroactive or impermissibly vague. The Court did not agree with Glaxo's argument that the USPTO had acted arbitrarily or capriciously in issuing the New Rules. In a potential preview of where the real fight might be as this case moves forward, the Court found that, based on the limited arguments presented in the preliminary injunction motion, neither party could claim a strong likelihood of success on arguments that the limits in the New Rules on claims and requests for continued examinations (RCEs) were impermissible.

### **Schedule Going Forward**

Glaxo proposed a summary judgment briefing schedule, and the other plaintiff in the combined case, Tafas, already had a briefing schedule for summary judgment. Both schedules would likely have produced a decision by Judge Cacheris sometime in January 2008. The USPTO, however, would not agree to these schedules and wanted more time, so the Judge ordered the parties to negotiate a briefing schedule. Given a longer briefing schedule and the strong likelihood that the losing side will appeal, a final judgment in the case might not happen until mid to late 2008. Depositions in the case have been tentatively scheduled for December.

### **USPTO Injunction**

Perhaps the most interesting part of the Order is that, until a final judgment is entered, the USPTO is "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 USPTO." While the language of this part of the injunction addresses the principle provisions of the New Rules on limits on continuations, claims and RCEs, there are numerous other provisions in the New Rules that have not been challenged in the lawsuit and might be outside the scope of this injunction, including:

- the requirement to identify the claim of priority for CIP cases (1.78(d)(3))
- the requirement to identify commonly owned "related cases" (1.78(f)(1))
- the imposition of a rebuttable presumption that claims of certain related cases are "patentably indistinct" (1.78(f)(2))—perhaps the most questionable of the provisions outside the injunction
- the ability of the USPTO to require the applicant to cancel claims in co-pending cases that are patentably indistinct (1.78(f)(3)) – already a requirement under the existing USPTO Rules
- the provisions for refunds based on cancellation of claims (1.117)
- the provisions for presenting a suggested restriction requirement (1.142(c))
- the provisions for reduction of patent term adjustment (1.704)—which raises the question of the extent to which the USPTO has authority to make rules that reduce patent term adjustment

### **Possible USPTO Reaction**

One question is whether the USPTO will try to implement some of these other provisions in a piecemeal fashion by issuing additional regulations, and whether such additional regulations could be issued without any notice or comment period. Another question is whether the scope of the additional injunction will prevent the USPTO from raising fees for continuing applications, RCEs and number of claims. During the notice and comment period for the New Rules, there were many who suggested that the USPTO should simply raise fees as a way to address the backlog issue, instead of promulgating limits. Certainly, raising fees for excess claims over 3/20 and RCEs and, for example, implementing a surcharge for continuing applications based on the number of claims of priority made to other nonprovisional applications, would accomplish much of the intended effect of the New Rules by the altering the economics for patent applications that fall outside the model patent application that the USPTO is trying to force applicants to prepare. The right of the USPTO to set fees for the prosecution of patent applications is generally accepted as within their regulatory authority. The question will be whether any attempts by the USPTO to raise fees or impose surcharges will be viewed as a violation of the scope or spirit of the preliminary injunction.

### **What's Next?**

There had been some speculation as to whether there might be a possibility that the effective date of the New Rules would be made retroactive to November 1, 2007, in the event that the USPTO does prevail. Given the relatively favorable treatment of the retroactive portion of the arguments by Glaxo, it seems highly unlikely that Judge Cacheris would issue a final order in this matter that did not limit the ability of the USPTO to make the effective date of the New Rules retroactive to November 1, 2007. The logistics and uncertainty of all of the actions by the USPTO in the interim also make any retroactive application of the effective date highly unlikely.

It is also unlikely that work done on currently pending cases in preparation for the New Rules will be completely wasted effort. Regardless of whether the USPTO prevails on the merits at summary judgment or appeal, further regulations that attempt to tighten up the requirements on patent applicants are almost a certainty. For now, getting important cases through the USPTO as quickly as possible seems to be the best way to keep ahead of the New Rules, whatever the outcome of the Glaxo lawsuit. Patent prosecutors may still want to think about the total number of claims in a new application and how the claims in a new application may be better positioned for possible restriction requirements.

In addition to the New Rules, a number of other Patent Office initiatives are still in the offing. The Information Disclosure Statement rules are still pending at the Office of Management and Budget, the Patent Reform Act is still pending in the Senate, and everyone will be trying to guess what the USPTO will do in response to the Glaxo injunction. We will of course be monitoring the progress of these initiatives along with any developments regarding the New Rules, but for now the only certainty about the fate of the patent process in the United States as we have known it is continued uncertainty.

Visit [www.ptslaw.com/uspto.cfm](http://www.ptslaw.com/uspto.cfm) for more information on the New Rules and ongoing updates on future developments.

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