

**Statement of**  
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**Submitted to the**  
**U.S. Patent and Trademark Office Roundtable**  
**on**  
**Reexamination**

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**Introduction**

Thank you for the opportunity to participate in the Office's Roundtable on reexamination. As a long-time supporter of a meaningful *inter partes* reexamination, I very much appreciate the Office's interest in carefully examining the present system and in trying to find ways to improve it. I am very willing to assist the Office in any way I can with this endeavor.

I speak today as a representative of my company, Guilford Pharmaceuticals. Presently, I am Senior Vice President & General Counsel of Guilford and oversee all legal matters, including intellectual property. Guilford is a publicly traded, proprietary drug company with approximately 320 employees and more than 130 U.S. patents. Guilford has two commercial products, GLIADEL® Wafer, used in conjunction with surgery to treat brain cancer, and AGGRASTAT® Injection, used to treat acute coronary syndrome, or ACS. We also have a number of product candidates in our pipeline, including ones for Parkinson's Disease, prostate cancer, and a new anesthetic, AQUAVAN™ Injection.

Guilford is not yet profitable. In other words, we spend far more on R&D than we make on our two commercial products. Thus, to fund R&D, we rely on investment capital—a result of others' belief that we will someday be profitable—and on funds from partnering with other pharmaceutical companies. A strong patent system is critical to our success. Without valid patents, Guilford would not be able to attract investment capital or partners

and thus would not have the resources required to invent and develop new, effective medicines.

### **The Challenges**

The value of patents and their ability to promote innovation depends upon having a strong patent system. And a strong patent system requires a meaningful, fair way to challenge the validity of patents without prohibitively costly, time-consuming litigation.

The new *inter partes* reexamination goes a long way to providing a very viable mechanism to challenge invalid patents without going to court. This is particularly true now that a third party can appeal to the Federal Circuit and now that *Portola Packaging* has been legislatively overruled. The Office played an important role in getting those changes enacted and should be applauded for their success. But challenges remain. First, the system in most cases cannot be used because it only applies to patents filed on or after November 29, 1999.

Second, even when *inter partes* reexamination is available, third parties often continue to use (and abuse) *ex parte* reexamination. By doing so, they can avoid the estoppel provisions of *inter partes* reexamination and still get multiple bites at the apple, or multiple opportunities to file comments in response to the patentee's arguments. They accomplish this by filing sequential reexamination requests based on the same "substantial new question of patentability." Once one reexamination request is granted, the Office in most if not all cases grants the subsequent requests and merges them into the first-granted reexamination. This abuse needs to be stopped, and it's in the Office's power to do so.

### **Recommended Changes**

Making certain changes in both our *inter partes* and *ex parte* reexamination systems would contribute to a fairer, more meaningful patent system. Several of these changes can be accomplished by the Office. Others would require legislation.

Most importantly, the 1999 legislation should be made retroactive so that it would apply to patents filed before that date. Until that change is made—or many years pass—*inter partes* reexamination cannot be used to challenge most patents. I believe the small number of filings is due in large part to this problem. Thus, the Office should lobby the Hill to make this change.

Second, *ex parte* reexamination should not be available to a third party to challenge a patent if *inter partes* reexamination is available. As noted previously, third parties abuse the system by effectively turning *ex parte* reexamination into *inter partes* reexamination. This should not be permitted when *inter partes* reexamination is available. They also abuse the system by attacking patents they previously unsuccessfully attacked in court. Because of the estoppel provisions, this cannot be done in *inter partes* reexamination. In the interest of fairness, it should not be permitted in *ex parte* either.

Even when *inter partes* reexamination is not available, third parties should not be permitted to abuse the system by filing multiple reexamination requests based on the same substantial new question or by again attacking a patent they unsuccessfully attacked in court. A second reexamination request should only be granted when there really is a substantial NEW question of patentability—not the same question raised in a previous reexamination request. It's not fair to the patentee and not what the system was designed for. *Ex parte* reexamination should be just that—*ex parte*.

Third, the Office should be required to complete reexamination in an expeditious manner, for example, within 18 months of the filing of the request. To make reexamination a viable option to litigation, it must be concluded in a reasonably short time. At present, I am not aware of any legislation proposing such a time limitation. While the “with special dispatch” language of 35 U.S.C. 314 (c) is helpful, it does not go far enough to ensure reexaminations will be sufficiently expedited. The Office could address this issue without legislation by defining “with special dispatch” in its regulations.

### **Other Recommended Amendments**

In addition, while not necessary to provide a fair and meaningful alternative to litigation, including reexamination of section 112 issues, other than best mode, should be considered. The PTO has expertise in determining whether a patent teaches how to make and use an invention, whether the patent shows the inventor had possession of the invention at the time the application was filed, and whether the claims are sufficiently clear and concise. On the other hand, the PTO has difficulty in evaluating whether the best mode of practicing the invention has been disclosed. This issue brings in questions of intent to conceal—questions better addressed by the courts and ones that would unduly lengthen reexamination. Section 101 issues should not be included either. As the Supreme Court held in *Diamond v. Chakrabarty*, “anything under the sun made by man” is patentable. Thus, bringing in section 101 would unduly lengthen the procedure to address an issue that seldom should bar patentability.

### **Oppositions as an Alternative to Reexaminations**

Guilford opposes adopting an opposition system in lieu of a fair and meaningful reexamination. While adding oppositions to the system as an alternative way to challenge the validity of newly issued patents may have merit, eliminating *inter partes* reexamination would be a mistake. These two mechanisms are very different and complementary: Reexamination is of limited scope for the life of the patent; and an opposition is typically of much broader scope for a very limited time, usually 9 months to a year after a patent issues. Further, it is difficult to imagine oppositions will be concluded quickly, as they typically are more trial-like and address more issues.

Guilford, and I believe companies like Guilford, must have a way to challenge a patent throughout its enforcement period, not just for a very short time after issuance. Today we’re focusing on neurological and hospital-based products, but we don’t know what technologies we’ll be working in tomorrow. Small companies like ours cannot afford to monitor all patents in areas they may work in someday or to oppose all patents that may potentially present a roadblock at some later time.

### **Conclusion**

To conclude, what Guilford is seeking from the Office is: (1) The ability to challenge patents filed before November 29, 1999; (2) As a patent holder, the assurance we'll not be harassed by third party abusive challenges to our patents through *ex parte* reexamination; (3) The assurance that both *ex parte* and *inter partes* reexaminations will be concluded quickly; and (4) The continued ability to challenge the validity of others' patents throughout their enforcement period.

Thank you.