PHARMACEUTICALS AT THE PATENT TRIAL & APPEAL BOARD

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INTRODUCTION

The impact of the Patent Trial and Appeal Board (PTAB) on U.S. patent litigation is undeniable. That impact has not been parallel across industries, however. The pharmaceutical industry has been slower than other industries to embrace *inter partes* reviews (IPR). But that appears to be changing. The most recent PTAB statistics show a significant uptick in IPR use for pharmaceutical patents. A vast majority of these pharmaceutical patent matters involve patents listed in the Orange Book, and today, many brand pharmaceutical companies are now facing parallel challenges to their patents in the U.S. district courts and PTAB.

Patent litigation under the Hatch-Waxman Act raises unique issues stemming from the interplay between the often parallel legal and regulatory processes. Among those issues are the critically important 30-month stay of final approval for ANDAs filed with Paragraph IV certifications, and the 180-day exclusivity for first-filed ANDAs. The increasing prevalence of IPR challenges during the pendency of such litigation is likely to further complicate the legal-regulatory interplay. Understanding of these issues will be critical for pharmaceutical companies in developing successful PTAB strategies.

To assist with that strategy, this guide explores key statistics and case studies that reveal how the PTAB is handling pharmaceutical patents and provides an overview of proactive measures unique to pharmaceutical companies involved in litigation before the PTAB, particularly during ongoing litigation in the U.S. district court regarding the same patent. The guide also examines advantages and disadvantages of using IPRs in biosimilars patent litigation.

The guide supplements Goodwin Procter's *PTAB Post Grant Proceedings: A Tactical Guide for Practitioners* and *Biosimilars: A Guide to Regulatory and Intellectual Property Issues.*