Inter Partes Review Facilitated Competition and Price Reductions for Opioid Addiction Treatment

Inter partes review of a patent covering a treatment for opioid addiction enabled a tenfold increase in competition and a 50% decrease in the cost of treatment.

Background

- In 2008, Reckitt Benckiser, a British pharmaceutical company, made more than $540 million from an opioid addiction treatment called buprenorphine, marketed as Suboxone. Its exclusive rights to market the drug ended in 2009, exposing it to competition from generic versions.
- To protect its profits, Reckitt Benckiser introduced a “sublingual film” formulation that was covered by new patents, protecting it from generic competition until at least 2023. Despite doubts about the film’s safety and efficacy, the company falsely touted its superiority to the tablet formulation, which succeeded in transitioning most users to the sublingual film.
- Eventually, Reckitt Benckiser’s successor company, Indivior, faced legal action and financial penalties for fraudulent marketing practices. But its patents remained intact.

Inter Partes Review

- After granting a petition for Inter Partes Review (IPR), the Patent and Trial Appeal Board (PTAB) concluded that one of the key patents on the sublingual film product was invalid due to obviousness (i.e. it would have been obvious to make based on pre-existing scientific knowledge), and the Federal Circuit affirmed its decision.
- A subsequent IPR proceeding invalidated an additional patent on the same product, and the Federal Circuit affirmed that decision as well.

Impact on Price and Competition

- After IPR and other lawsuits opened the door to generics, competition surged and prices for Suboxone film products precipitously. Today, at least thirteen generics are approved for sale and prices are 50% less than the peak brand price.
Conclusion

- IPR proceedings were critical to opening the door to generic competition years before the patents, if unchallenged, would have expired.
- After the Federal Circuit affirmed the IPR decisions, prices of opioid addiction treatment fell by 50%, ensuring more patients could receive the treatment they needed.
- The availability of IPR proceedings was essential to stopping a patent holder’s brazen efforts to stifle competition and charge monopoly prices long after its rightful term expired.