

# CASE STUDY: SUBOXONE PATENTS

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## 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

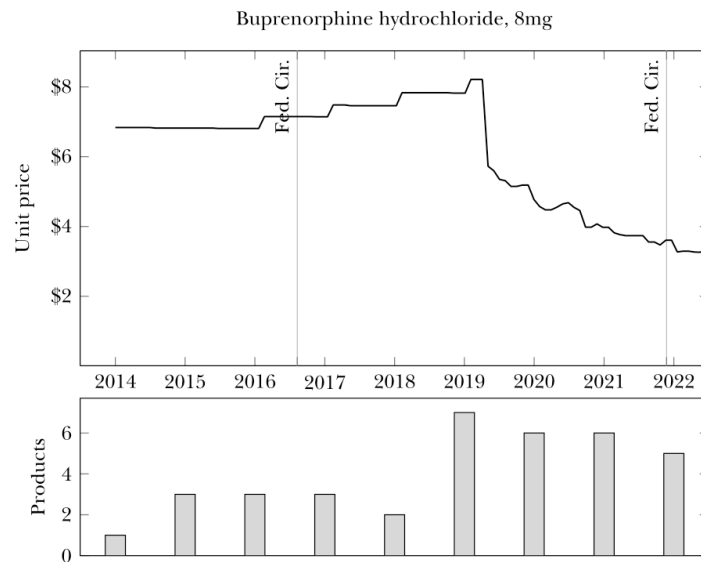
- In 2008, Reckitt Benckiser, a British pharmaceutical company, made more than \$540 million from an opioid addiction treatment called **buprenorphine**, marketed as Suboxone. Its exclusive rights to market the drug ended in 2009, exposing it to competition from generic versions.
- To protect its profits, 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**.



The tables above show the price and number of competing products before, during, and after IPR.

## 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.

Source: Duan, Charles, *On the Appeal of Drug Patent Challenges*, 2 Am. U. L. Rev. 1177, 1198-1200 (2023), available at: <https://ssrn.com/abstract=4406404> or <http://dx.doi.org/10.2139/ssrn.4406404>.



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