CASE STUDY: GLATIRAMER PATENTS

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How Inter Partes Review Allowed Generic Entry and Reduced the Price of a Treatment for Multiple Sclerosis

Inter partes review of patents covering a treatment for multiple sclerosis facilitated **generic competition that brought the drug's price down by 75%.**

Background

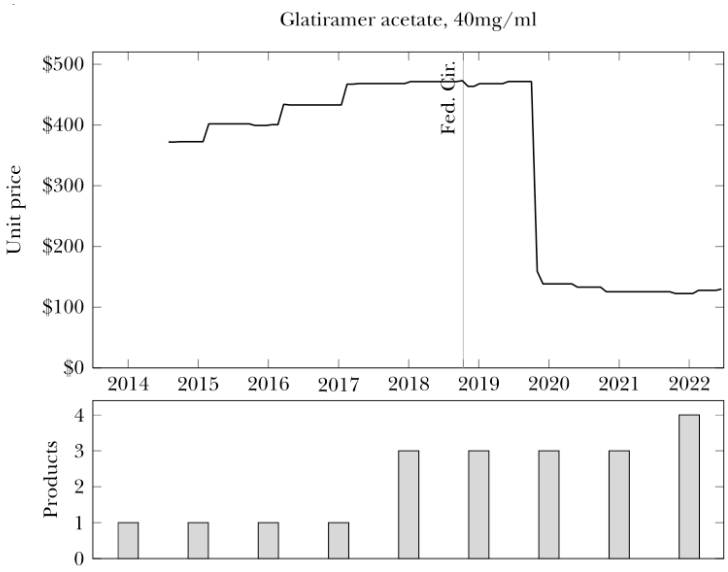
- Glatiramer acetate is a treatment for **multiple sclerosis**.
- Although the treatment was available in a generic form, Yeda Pharmaceuticals held patents on an **effective dosing regime**, which it marketed as **Copaxone 40mg**.

Inter Partes Review

- Mylan filed a petition for Inter Partes Review (IPR), and after granting the petition, the Patent and Trial Appeal Board (PTAB) found the **patents invalid**.
- The PTAB concluded that the patented 40mg dosing regimen was **obvious**, and therefore **unpatentable**, because extensive scientific evidence made it the only reasonable choice for researchers in the field well before the underlying patent was filed.
- The **Federal Circuit agreed** and affirmed the PTAB's decision.
- A **separate district court case** also found the patents invalid, but that **proceeding took more than twice as long as the IPR** (nearly three years compared to just over one year). Moreover, that proceeding was limited to the particular patent claims Yeda Pharmaceuticals asserted in that case, while the IPR could include all of the patent's claims, including any reserved for future litigation.

Impact on Drug Prices

- After the PTAB's decision was affirmed, generic competitors quickly entered the market, and prices declined steeply, **falling 97% below the brand price.**
- Generic competition began shortly after the IPR concluded, **lowering prices by about 75%**.



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

Conclusion

- IPR enabled generic competitors to enter the market for multiple sclerosis treatment, and this competition brought the **price of treatment down by 75%.**

Source: Duan, Charles, *On the Appeal of Drug Patent Challenges*, 2 Am. U. L. Rev. 1177, 1205–07 (2023), available at: https://ssrn.com/abstract=4406404 or http://dx.doi.org/10.2139/ssrn.4406404.