CASE STUDY: RIVASTIGMINE PATENTS

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How Inter Partes Review Reduced the Price of a Dementia Treatment

After Inter Partes Review of a patent on a treatment for dementia, **prices fell by 75%.**

Background

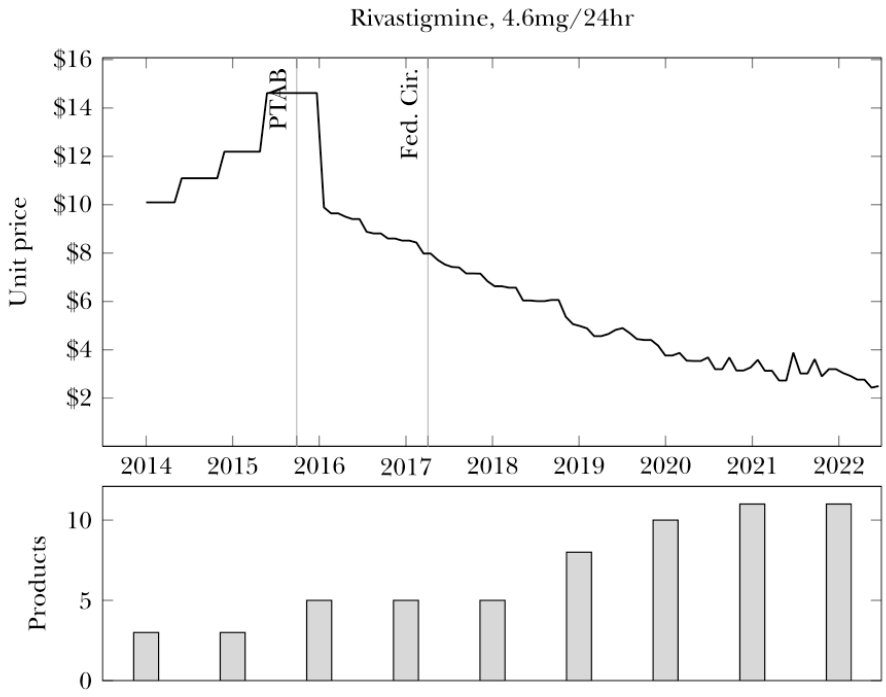
- In the 1980s, rivastigmine was discovered as a treatment for dementia.
- In 1998, **Novartis** sought **patents** for delivering rivastigmine via a transdermal patch, marketed as the **Exelon Patch.** These patents focused on combining rivastigmine with an antioxidant as patches containing only rivastigmine were already known and therefore unpatentable.
- In 2014, Novartis' patents were **challenged** in **district court**, but the **judge declined to invalidate** them after admitting the evidence was so difficult to understand that he had to rely on witness credibility instead of scientific facts.

Inter Partes Review

- The same Novartis patents were subsequently **challenged—and invalidated**—in Inter Partes Review (IPR).
  - In its 2017 decision, the Patent and Trial Appeal Board (PTAB) explained that **combining rivastigmine with an antioxidant was obvious** because basic scientific principles taught such a combination was necessary to prevent rivastigmine from degrading.
- The **Federal Circuit** not only **affirmed the PTAB's decision**, but commended it for relying on "[a]mple record evidence."
  - The Federal Circuit also highlighted the **key distinctions between the PTAB and district court decisions**:
    - the PTAB had a better-developed factual record and more capacity to consider it.
    - The PTAB's had more capacity to consider the facts both because of its technical expertise and because of its freedom from the presumption of patent validity that applies in district courts.

Impact on Price and Competition

- Generic entry swiftly followed the invalidation of Novartis's patent, leading prices of rivastigmine patches for treating dementia to **fall by 75%**.



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

Conclusion

- The IPR proceeding that invalidated Novartis's patents on the Exelon patch had a swift and significant impact, **facilitating generic entry and reducing prices by 75%.**
- The IPR system was critical because it enabled the **PTAB and Federal Circuit to receive and consider a richer presentation of scientific facts** from which to reach a better-reasoned result than was possible in district court.
- This underscores the unique and essential role of IPR in **preventing invalid patents from unduly impeding competition, inflating prices, and obstructing access to medical care**.

Source: Duan, Charles, *On the Appeal of Drug Patent Challenges*, 2 Am. U. L. Rev. 1177, 1196—98 (2023), available at: https://ssrn.com/abstract=4406404 or http://dx.doi.org/10.2139/ssrn.4406404.

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