

CASE STUDY: PRASUGREL PATENTS

PUBLIC INTEREST PATENT LAW INSTITUTE  MARCH 2024

How Inter Partes Review Drastically Lowered the Price of a Drug for Treating Cardiovascular Disease

Inter partes review of a patent covering a drug for cardiovascular disease opened the door to generic competition that brought the drug's **price down by 97%**.

Background

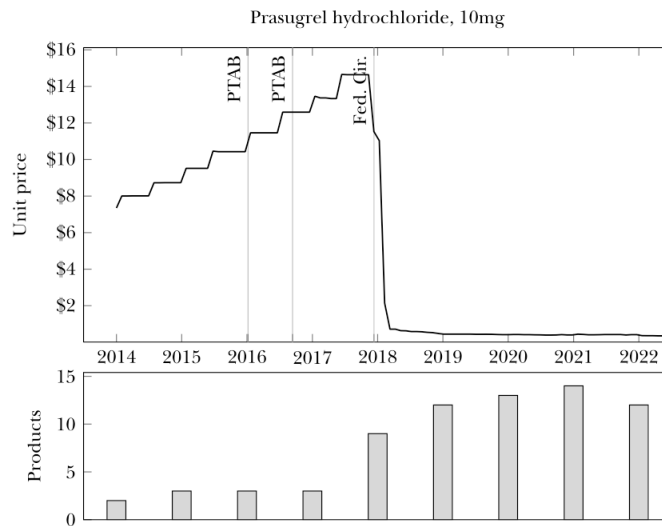
- Prasugrel is an **anti–blood clot drug** used to treat cardiovascular disease, marketed under the name **Effient** by Daiichi Sankyo.
- Although Daiichi Sankyo's patent on Effient's active ingredient expired in 2017, the company held **additional patents on methods of using Effient with aspirin** that did not expire until 2023.
- These additional patents effectively gave Daiichi Sankyo a **monopoly** over the drug for **six years beyond the term of its original patent**.

Inter Partes Review

- After granting a petition for Inter Partes Review (IPR), the Patent and Trial Appeal Board (PTAB) concluded that the **patent was invalid**.
- The PTAB explained that the **combination of aspirin and prasugrel was obvious**, and therefore not patentable, because aspirin, a well-known blood thinner, had frequently been combined with anti-clotting agents as a treatment for cardiovascular disease. As such, combining aspirin with a “more potent, and preferred . . . anti-platelet drug, i.e., prasugrel” would have been the **predictable next step for an ordinary researcher in the field to take**.
- The **Federal Circuit agreed** with the PTAB and affirmed its decision in 2018.

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**.
-



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

Conclusion

- Because of IPR, generic competitors were able to **enter the market six years before they could have** if Daiichi Sankyo's later-expiring patents on methods of use had remained unchallenged.
- After the Federal Circuit affirmed the IPR decisions, prices of prasugrel, a treatment for cardiovascular disease, fell by 97%, generating **huge savings for patients and payers**.

Source: Duan, Charles, *On the Appeal of Drug Patent Challenges*, 2 Am. U. L. Rev. 1177, 1204–05 (2023), available at: <https://ssrn.com/abstract=4406404> or <http://dx.doi.org/10.2139/ssrn.4406404>.



info@piplus.org