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.