How Inter Partes Review of Zytiga Patents Drastically Decreased Prices of Prostate Cancer Medication

Inter partes review of a patent covering Zytiga—a prostate cancer drug—enabled drug prices to decline by 80% to 98%

Background

- **Abiraterone acetate**, used to treat prostate cancer, has been known since at least 1994.
- Patents on the compound expired around 2014.
- **Janssen Biotech** markets and holds patents to a formulation called **Zytiga**, in which abiraterone is prescribed for use in combination with “a therapeutically effective amount of prednisone,” a well-known steroid.
- The **World Health Organization** lists the drug as one of the “essential medicines for priority diseases” that constitute “minimum medicine needs for a basic healthcare system”.

Inter Partes Review

- In 2017, Argentum Pharmaceuticals, a would-be generic manufacturer, challenged the Zytiga formulation patent in an inter partes review proceeding at the Patent Trial and Appeal Board (PTAB).
- In 2018, the PTAB found the Zytiga patent obvious, and therefore invalid.
  - The PTAB based its decision on evidence that both abiraterone and prednisone were individually considered promising prostate cancer treatments and that combining anti-cancer treatments with steroids was standard practice before Janssen even applied for its patent.
  - The Federal Circuit agreed and affirmed the PTAB’s decision the following year.

Impact on Drug Prices

- **Before** the inter partes review, Janssen Biotech charged approximately $88 per dose of Zytiga.
- **After** the Federal Circuit affirmed the PTAB’s decision to invalidate the Zytiga patent, generic manufacturers quickly entered the market, offering comparable drugs for a price of $2–19 per dose.
The tables above show the price and number of competing products in relation to the PTAB and Federal Circuit decisions in the inter partes review.

**Conclusion**

The inter partes review of the Zytiga patent ultimately enabled savings of 80% to 98% on an essential medication for prostate cancer.