

CASE STUDY: ZYTIGA PATENTS

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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

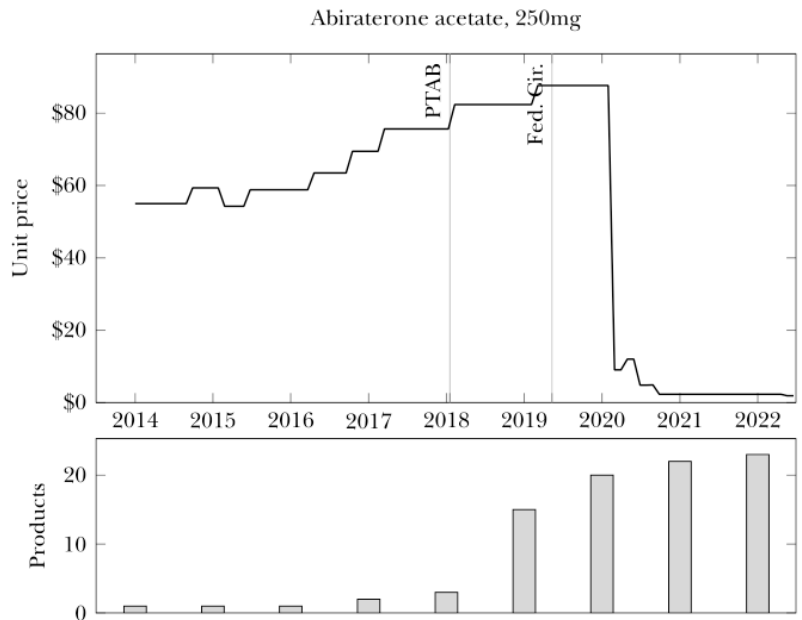
- **Abiraterone acetate**, used to **treat prostate cancer**, has been known since at least 1994.
- Patents on the compound **expired around 2014**.
- **Janssen Biotech** markets and holds patents to a formulation called **Zytiga**, in which abiraterone is prescribed for use in combination with “a therapeutically 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 health-care 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**.

Source: Duan, Charles, *On the Appeal of Drug Patent Challenges*, 2 Am. U. L. Rev. 1177, 1203-04 (2023), available at: <https://ssrn.com/abstract=4406404> or <http://dx.doi.org/10.2139/ssrn.4406404>.



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