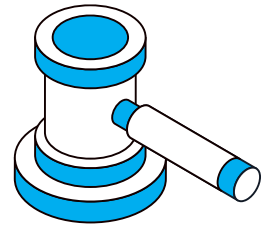
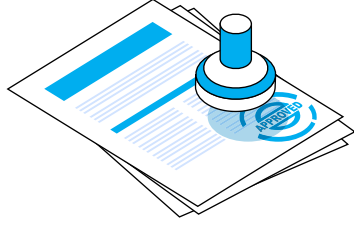


By the Numbers:

IPR Speeds Patient Access to Lower-Cost Medicine

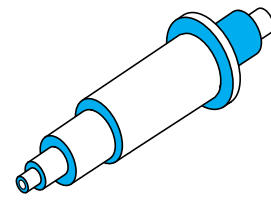
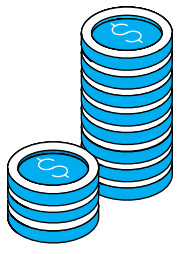
AAM Members Routinely Use the IPR Process

The inter partes review (“IPR”) process was created by the America Invents Act (“AIA”) to allow the Patent and Trademark Office (“PTO”) to correct mistakes in issuing patents.



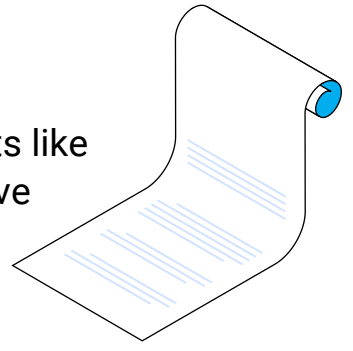
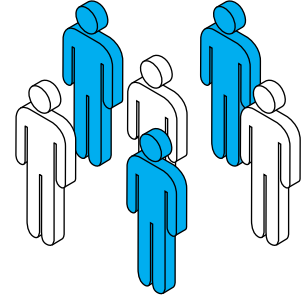
The PTO reviews approximately **600,000 applications every year**,¹ and yet examiners only spend approximately **19 hours per application**.²

IPR is a critical tool to help address patent thickets in the biologics space and to allow the PTO to correct its mistakes. A frequently cited example of a patent thicket is Humira®, a biologic indicated for rheumatoid arthritis that resulted in **132 issued patents** and a litigation with **74 asserted patents**.³



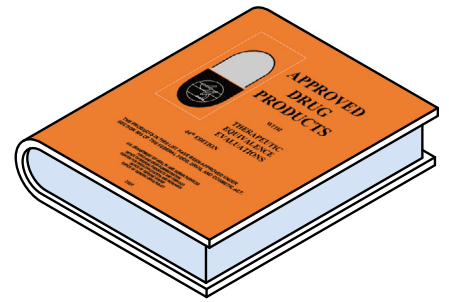
Between 2015-2019 alone, the “delayed entry of biosimilars” due to overpatenting like Humira® “cost the U.S. health care system an astounding **\$7.6 billion in lost savings**.”⁴

Because of these patent thicketing practices, approximately **868 IPR petitions** have been filed against Orange-Book listed patents (those covering small molecules) and biologic patents like those covering Humira®.⁵ An additional **636 IPR petitions** have been filed against patents classified as “Other Bio/Pharma.”



IPR is a critical tool for generic and biosimilar competition. In particular, AAM’s members regularly and routinely use this process. **Fifteen (15) different members** of AAM are listed as the petitioners in **approximately 201 IPR proceedings** challenging Orange-Book listed patents and biologic patents.⁶

Orange Book patents (i.e., patents on branded pharmaceuticals) account for less than .2% of all patents but **3% of all PTAB petitions**, which means that **drug patents are over 15 times more likely to be challenged at the PTAB**. Similarly, the U.S. biopharmaceutical sector directly accounts for **1.6% of U.S. GDP** but **7% of PTAB petitions**, so biopharma uses the PTAB more than four times as much as would be predicted based on the industry’s size.



Example—Zytiga®: IPR has accelerated access to lower-cost medicine and saved patients and the healthcare system billions. For example, with regard to the prostate cancer drug Zytiga®—which had net sales of as much as **\$154 million per month** before generic entry⁷—IPRs helped allow for the launch of lower-cost generic versions of the drug in 2019, approximately 8 years before the expiration of the patent that was invalidated in IPR.⁸ Brand sales pre-generic entry were \$149 million in Oct 2018; by Sep 2021, total sales (brand and generic) were less than \$38mn as a direct result of generic competition via IPR.⁹ As commentators have noted, “IPR . . . enabled almost **98% savings** on a drug that the World Health Organization lists as one of the ‘essential medicines for priority diseases’ that constitutes ‘minimum medicine needs for a basic healthcare system.’”¹⁰

Example—Effient®: Similarly, with regard to the blood thinning drug Effient®, AAM member Accord successfully used IPR to invalidate two secondary patents directed to using Effient® in connection with an age-old molecule, aspirin.¹¹ Generic products proceeded to enter the market at prices **97% below the brand price**.¹² Brand company Lilly noted in SEC filings that generic entry “caused a rapid and severe decline in revenue” that had a material effect on its operations.¹³

Example—Lantus®: With regard to Lantus® (insulin glargine), the brand company (Sanofi) held device patents on their SoloStar® injector pens that the First Circuit Court of Appeals characterized as an “extension of Sanofi’s monopoly.”¹⁴ The PTAB proceeded to invalidate the device patents, and the decision was affirmed by the Federal Circuit.¹⁵ Biosimilar versions of Lantus® were launched while the Federal Circuit appeal was pending at “pricing of **\$147.98 for five pens compared to \$425.31 for Lantus SoloStar**.”¹⁶

References

- USPTO, *Nonprovisional (Utility) Patent Application Filing Guide (June 2023)*, available at <https://www.uspto.gov/patents/basics/apply/utility-patent#:~:text=A%20nonprovisional%20application%20is%20examined,copies%20of%20other%20USPTO%20publications.>
- Lisa Larrimore Ouellette, *Should Patent Examiners Get More Time*, JOTWELL (Mar. 13, 2019), <https://ip.jotwell.com/should-patent-examiners-get-more-time.>
- Complaint at ¶ 1, *AbbVie v. Boehringer Ingelheim Int'l GmbH*, No. 1:17-cv-01065-MSG-RL (D. Del. Aug. 2, 2017).
- Biosimilar Council, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients: Part I* at 4 (June 2019), <https://biosimilarscouncil.org/wp-content/uploads/2019/10/Failure-to-Launch-Part-1.pdf>.
- USPTO, *PTAB Orange Book Patent/Biologic Patent Study FY24 Q2 Update (through March 31, 2024)* at 4, https://www.uspto.gov/sites/default/files/documents/orange_book_biologics_study_march2024.pdf.
- USPTO, Patent Trial and Appeal Board Case Statistics (P-TACTS) System, <https://www.uspto.gov/patents/ptab/about-p-tacts>.
- David Miller, et al., *The Costs of Delayed Generic Drug Entry: Evidence from a Controversial Prostate Cancer Drug Patent*, 37(3) J GEN. INTERNAL MED. 668, 669 (2021), <https://link.springer.com/article/10.1007/s11606-021-07000-3>.
- Eric Sagonowsky, *J&J's blockbuster Zytiga falls to patent challenge, boosting threat of 2018 generics*, Fierce Pharma (Jan. 18, 2018), <https://www.fiercepharma.com/legal/j-j-s-zytiga-falls-to-patent-challenge-opening-possibility-2018-generic-competition>.
- Source: IQVIA data.
- Charles Duan, *On the Appeal of Drug Patent Challenges*, 72 AM. UNIV. L. REV. 1177, 1204 (2023), https://aulawreview.org/wp-content/uploads/2023/09/3_Duan_Print.pdf.
- Federal Circuit Affirms the Invalidity of Effient® Patents*, Sughrue Mion PLLC (Dec. 13, 2017), <https://www.sughrue.com/news/federal-circuit-affirms-the-invalidity-of-effient-patents>.
- Charles Duan, *On the Appeal of Drug Patent Challenges*, 72 AM. UNIV. L. REV. 1177, 1204 (2023), https://aulawreview.org/wp-content/uploads/2023/09/3_Duan_Print.pdf.
- Eli Lilly and Company Form 10-K for the fiscal year ended December 31, 2018, SEC, <https://www.sec.gov/Archives/edgar/data/59478/000005947819000082/lly-20181231x10xk.htm>.
- In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 3 (1st Cir. 2020).
- See *Sanofi-Aventis Deutschland v. Mylan Pharms. Inc.*, 2021 U.S. App. LEXIS 38483, at *2 (Fed. Cir. Dec. 29, 2021) (per curiam); *Sanofi-Aventis Deutschland GmbH v. Mylan Pharms. Inc.*, 2021 U.S. App. LEXIS 38482, at *6 (Fed. Cir. Dec. 29, 2021) (per curiam); *Sanofi-Aventis Deutschland v. Mylan Pharm., Inc.*, 2021 U.S. App. LEXIS 38481, at *3 (Fed. Cir. Dec. 29, 2021) (per curiam) (nonprecedential).
- Charles Duan, *On the Appeal of Drug Patent Challenges*, 72 AM. UNIV. L. REV. 1177, 1204 (2023), https://aulawreview.org/wp-content/uploads/2023/09/3_Duan_Print.pdf.