

Keytruda's Patent Wall

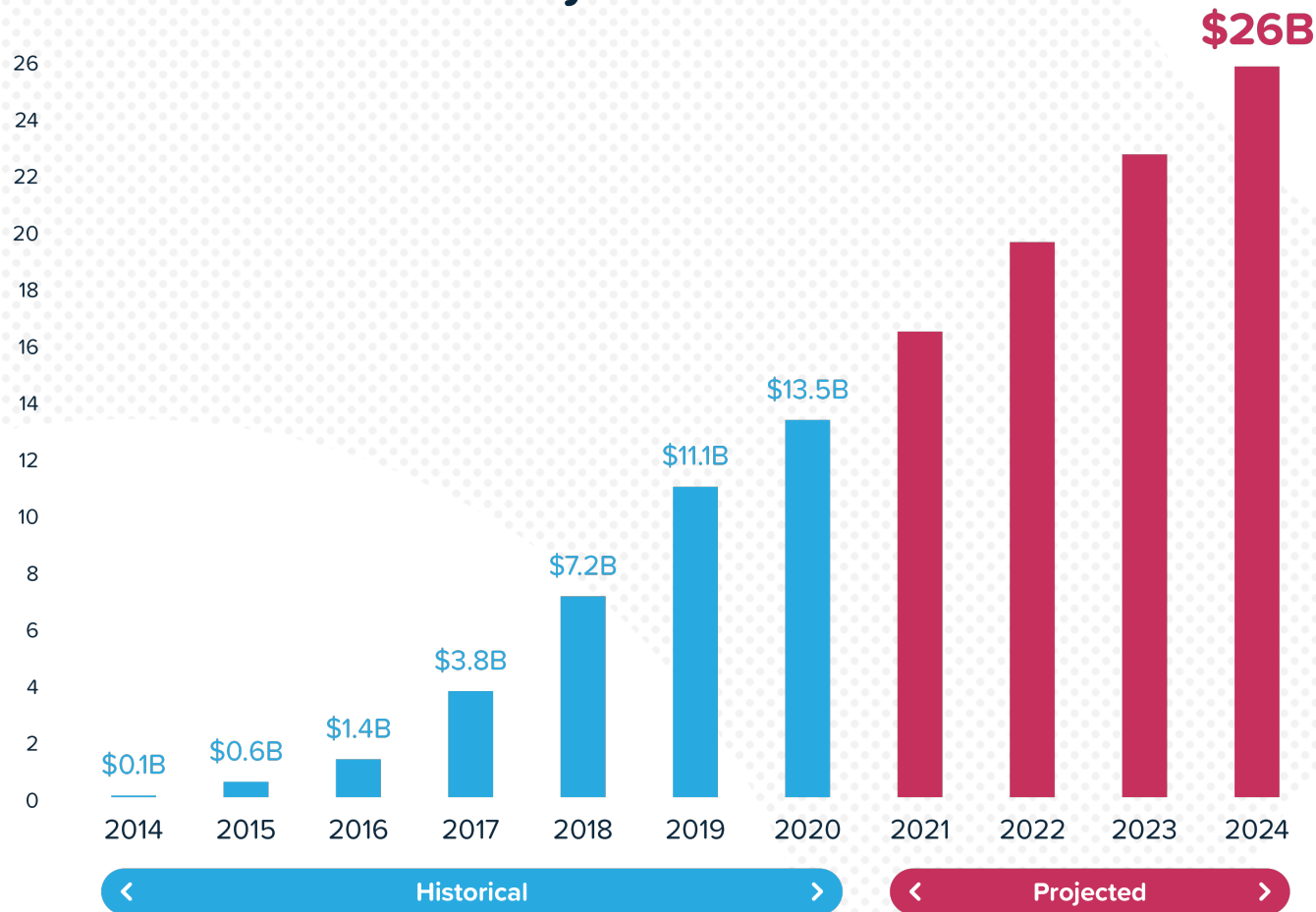
THE DRUG PATENT PROBLEM

Keytruda's patent wall lengthens its monopoly term by 8+ years.

Without competition, U.S. payers and taxpayers will spend an estimated \$137 billion on branded Keytruda during that time.

KEYTRUDA IS POISED TO BE THE TOP SELLING DRUG IN THE WORLD (AND AMERICA) BY 2024

Global Revenue for Keytruda



Indications: Keytruda has 31 separate FDA approvals for 19 different types of cancer.

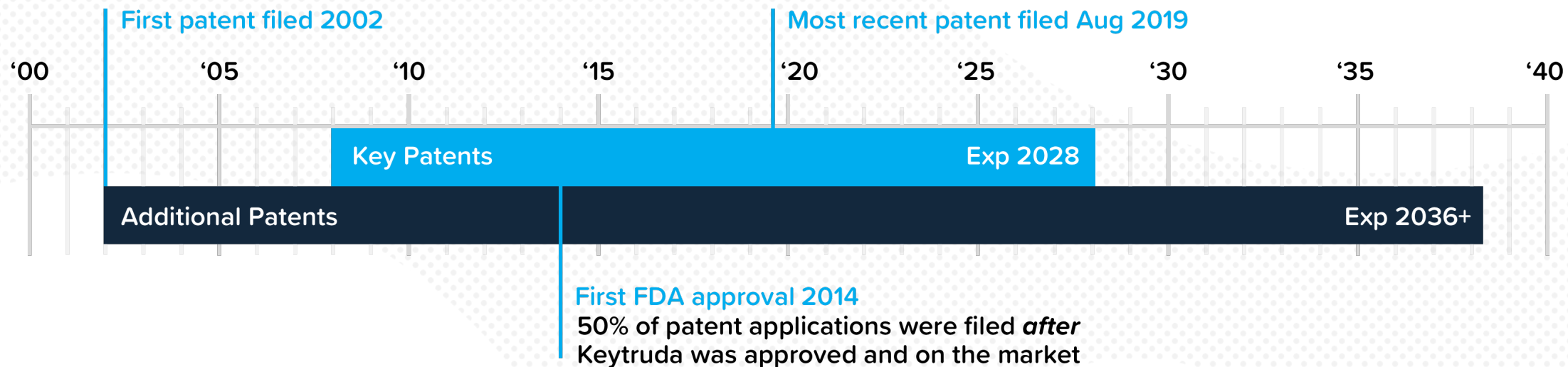
Price: Current annual list price is \$165,308 per person, an increase of 147% in the first 5 years on the market

Spending: \$21.7 billion total net U.S. sales between 2014 and 2020, with average annual growth of 106%

Forecast: Projected to become the top grossing drug in the world by 2024, with annual revenues of \$26 billion

KEYTRUDA HAS 35 YEARS OF PATENT PROTECTION . . . AND GROWING

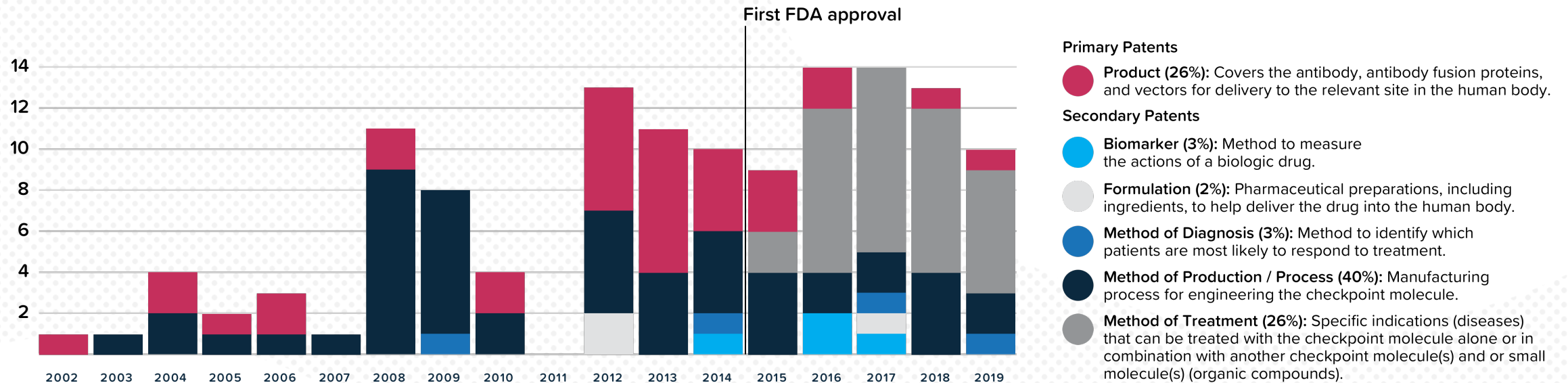
- **50%** of patent applications filed after FDA approval
- **129** patent applications filed, **53 granted**
- Patents granted give commercial exclusivity for **35 years**



35 years of patent protection

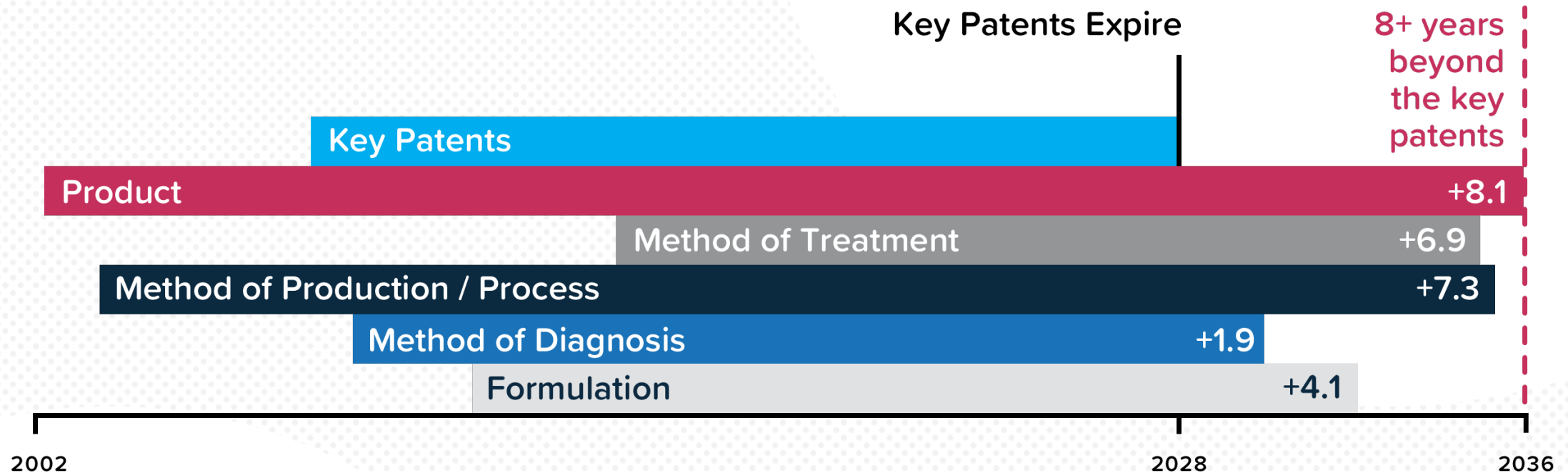


74% OF KEYTRUDA'S PATENTS ARE NOT FOR THE ACTIVE SUBSTANCE



Patents covering Keytruda's indications and manufacturing processes are being filed later in the drug's lifecycle in order to extend the total lifetime patent protection of the drug

PATENTS COULD EXTEND ITS MONOPOLY BY 8 YEARS AND COST AMERICANS AN EXTRA \$137 BILLION



During that extended period of time (2028-2036), we conservatively estimate Americans will spend **\$137 billion** on branded Keytruda.* We anticipate that more patents will be filed and granted on this drug as it obtains regulatory approval for a growing number of indications. This could further extend the monopoly on Keytruda and cost Americans more.

*Based on an I-MAK model of estimated total U.S. revenue/spending for Keytruda in the eight-year period from mid-2028 (the expiration dates of Merck's two key antibody and formulation patents) to Sep 2036 (the latest expiry of a currently granted patent). It assumes the annual growth in product revenue peaks in 2020 and steadily decreases from 15% to 1% annual growth from 2021 to 2028. From 2028 onward, the analysis conservatively assumes annual growth is only 1% through 2036, corresponding to annual revenue of approximately \$25 billion. There is no assumption of a biosimilar product entering the market in this time period.

KEY QUESTIONS FOR POLICYMAKERS

- Does the current regulatory system governing biologic drugs, the Biologics Price Competition and Innovation Act, incentivize companies to claim as many patents as possible in order to delay the outcome of litigation and biosimilar entry?
- Despite the passing of the recent Biological Product Patent Transparency Act, should all relevant patents for a biologic drug that would be enforced in litigation be listed in the Purple Book at the time the drug is approved?
- Should process and manufacturing patents that do not form part of the approved biologic drug application be allowed to extend the a company's exclusivity and prevent the entry of biosimilars?
- Should subsequent patents on biologic drugs covering new indications and process/manufacturing patents be considered inventive and be each given 20 years of separate patent monopoly if they cover subject matter that were already disclosed in the first patent?

Supplementary material for this report, including the methodology, is available at i-mak.org/keytruda.