

Imbruvica's Patent Wall

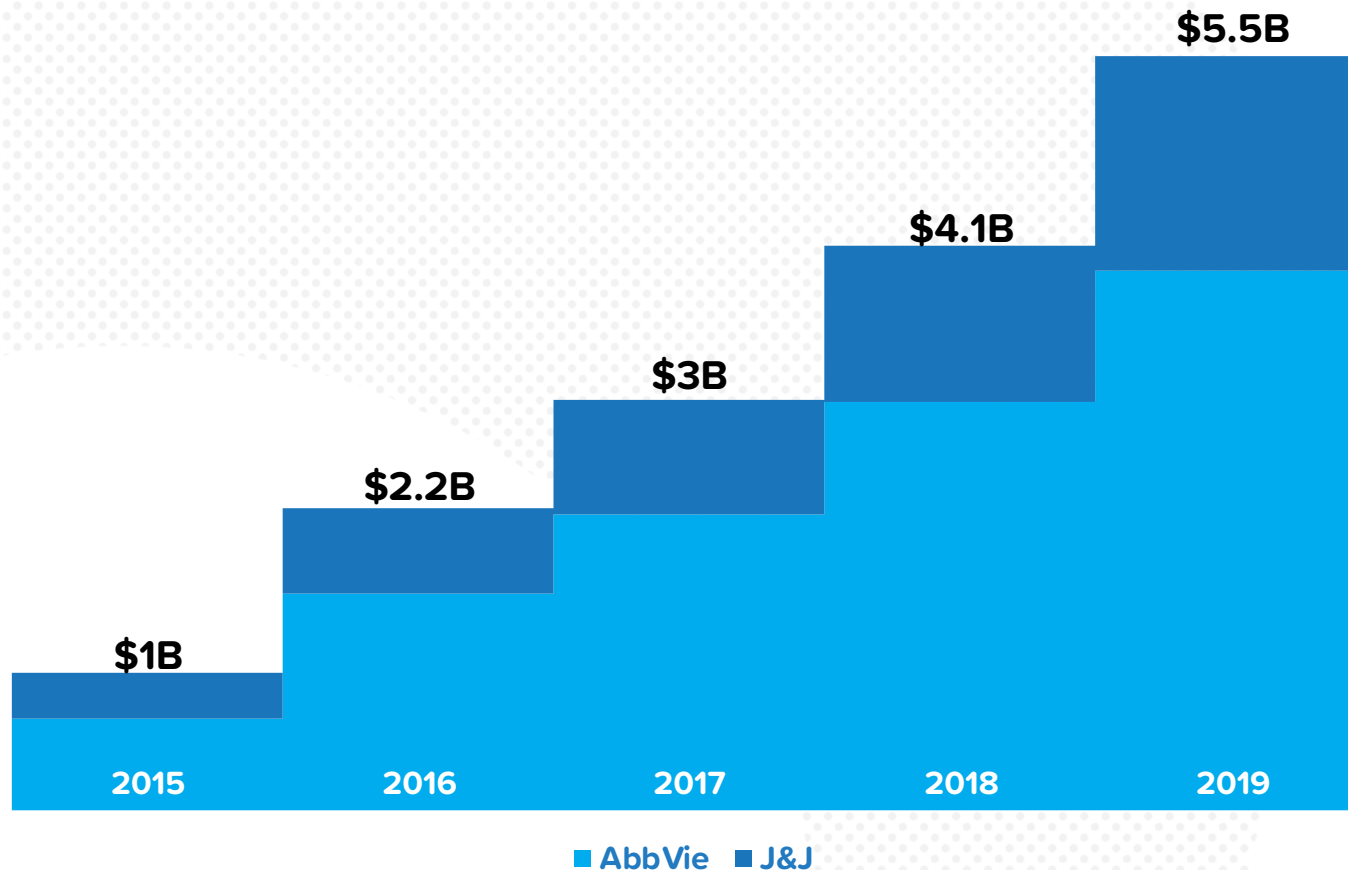
THE DRUG PATENT PROBLEM

Imbruvica's patent wall lengthens its monopoly term by 9+ years.

Without competition, U.S. payers and taxpayers will spend an estimated \$41 billion on branded Imbruvica during that time.

PRICING, REVENUE, AND GROWTH FORECAST

Revenue for Imbruvica in the U.S.



Indications: Treats a variety of B cell cancers, including leukemia and lymphoma

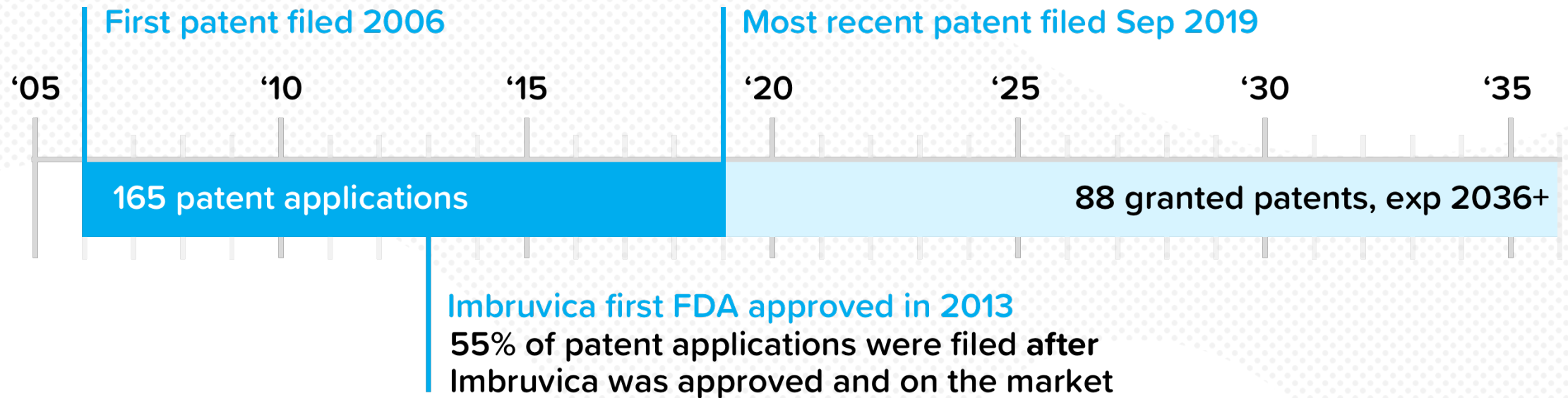
Price: Current non-discounted annual price is \$174,156 per person

Trend: Price has increased over 57% since 2013

Forecast: Projected to become the 4th highest grossing drug in the U.S. by 2024, with annual revenues of nearly \$9 billion

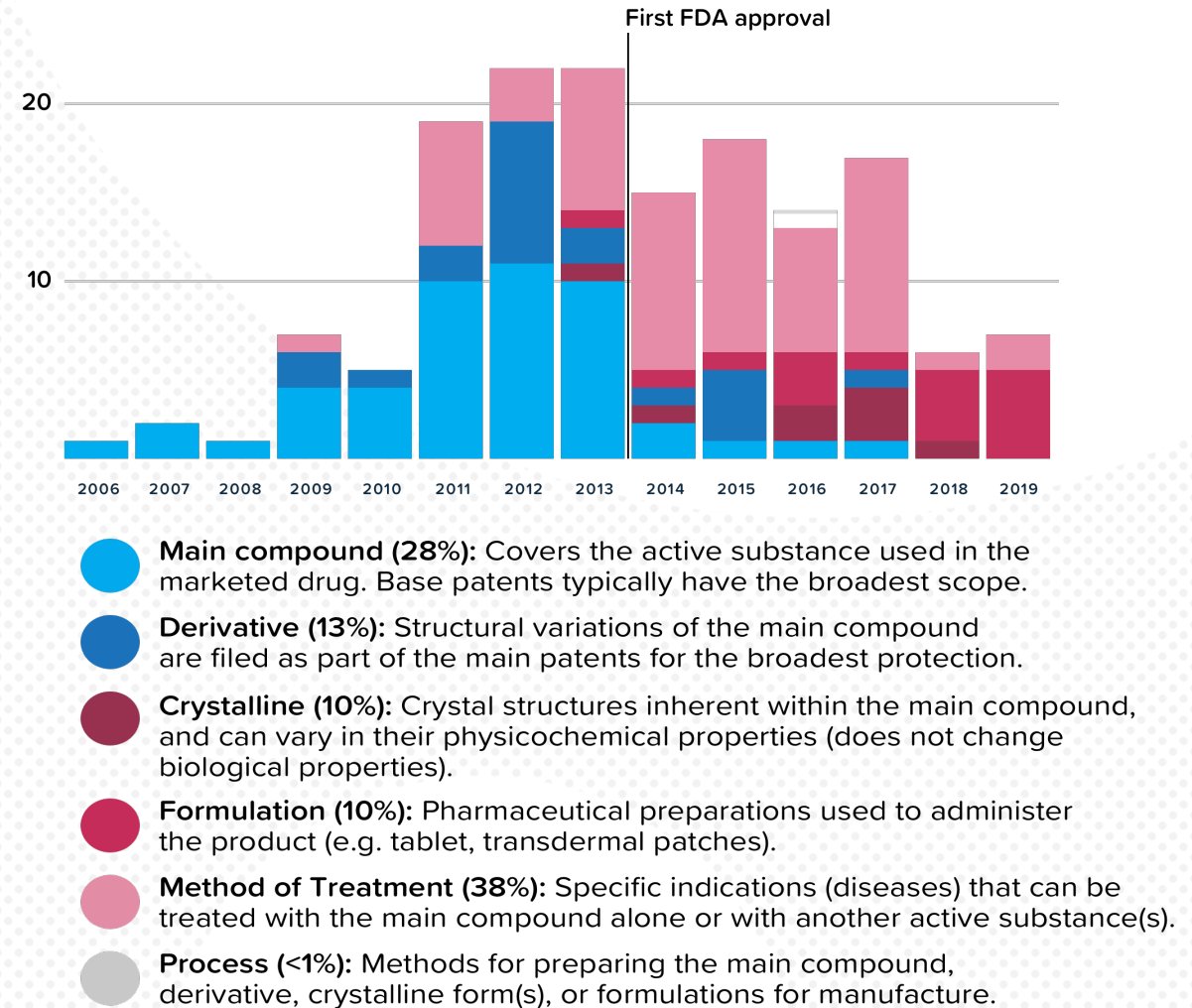
CURRENTLY 29 YEARS OF PATENT PROTECTION MAJORITY OF PATENT APPLICATIONS FILED AFTER FDA APPROVAL

- **165** patent applications filed, **88** granted
- Patents granted give commercial exclusivity for **29** years

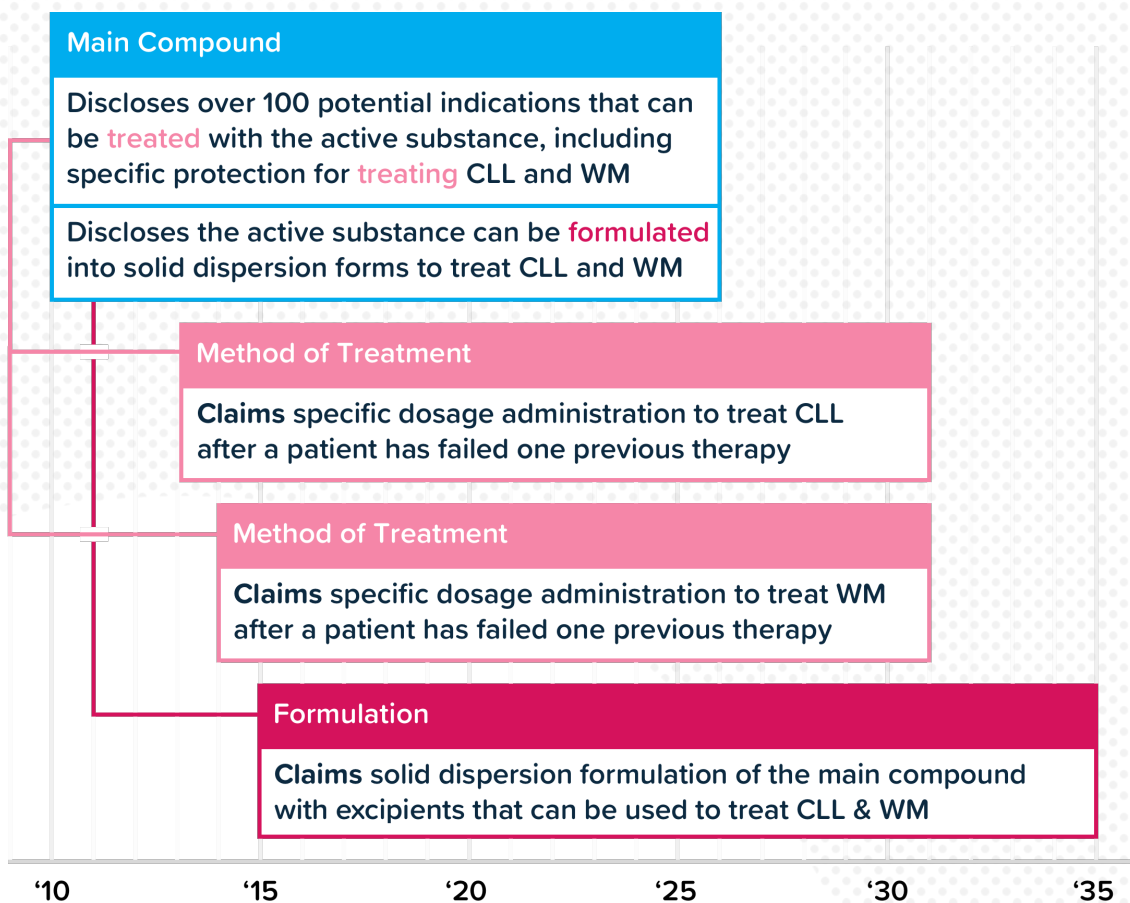


58% OF PATENTS FOR IMBRUVICA ARE NOT FOR THE ACTIVE SUBSTANCE

- **Before FDA Approval:** Majority of patent applications were for the active substance and its derivative compounds
- **After FDA approval:** Ongoing patent applications for additional indications and formulations describing elements of earlier patents more specifically



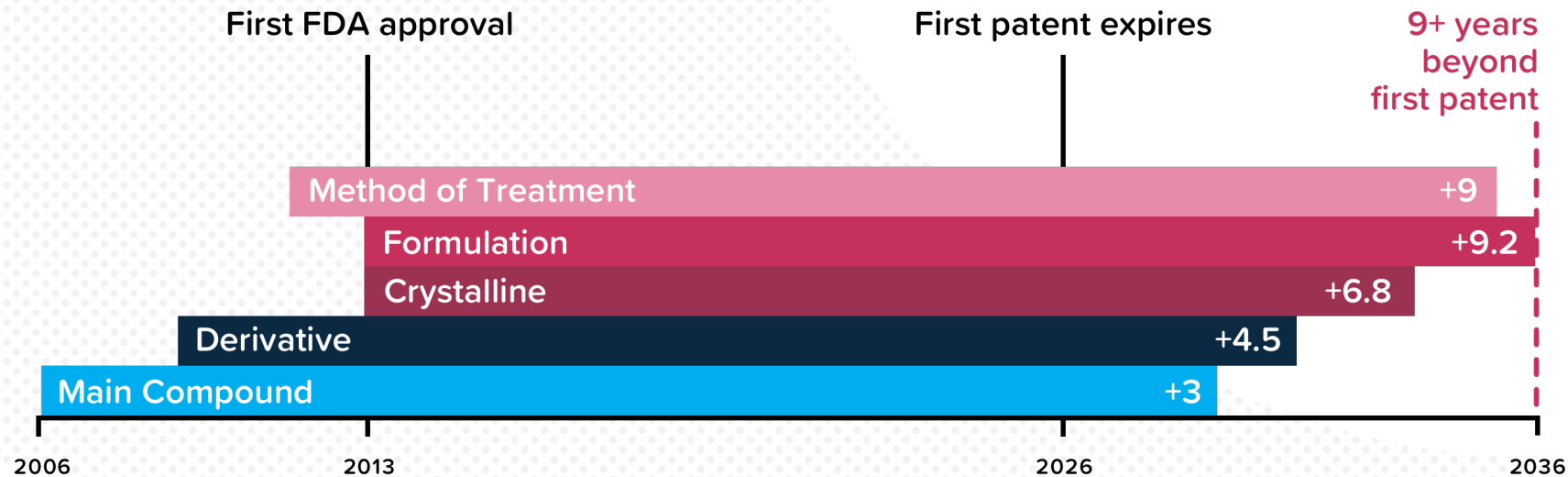
DEEPER ANALYSIS REVEALS A “DRIP-FEED” PATENTING STRATEGY



WM = Waldenstrom macroglobulinemia. CLL = Chronic lymphocytic leukemia.

Knowledge that is broadly disclosed in early patent applications is defined ever more narrowly and specifically in a spread of subsequent patent applications.

INDICATIONS AND FORMULATIONS LENGTHEN IMBRUVICA'S MONOPOLY TERM BY 9+ YEARS



Without competition, during the 9 years of extra patent protection spending on branded Imbruvica is estimated to reach at least **\$41 billion**.* We anticipate that more patents will be filed and granted on this drug, which could extend the monopoly further.

*Based on granted patents identified as of November 2019. I-MAK model of estimated revenue/spending for Imbruvica in the ten-year period from 2027-2036. Assumes total U.S. revenue for Imbruvica increases until 2024 when it reaches a peak of \$8.7B (\$6.2B AbbVie and \$2.5B J&J), which is consistent with various market forecasts (see EvaluatePharma, May 2019). From 2025 onward, the model conservatively assumes there are decreases of 10% annually in total U.S. revenue/spending through 2036, based on new products entering the market and reduced market share for Imbruvica. There is no assumption of a generic product entering the market in this time period.

ONE-SIZE-FITS-ALL PATENT SYSTEM ENABLES THE “DRIP FEED” PATENTING STRATEGY TO LENGTHEN MONOPOLY PERIOD

- **The current patent system does not differentiate between the types of patents.**
The first patent on the main compound and subsequent patents receive the same 20 years of exclusivity, regardless of what was already known at the time the first patent was filed.
- As long as subsequent patents are written specifically enough to be considered outside the scope of disclosure of the first patent(s), **the potential to keep stacking additional patents on a single, already patented active substance is limitless.**

SOME KEY QUESTIONS

- **Are the standards for what is considered inventive too low?** Does Congress need to redefine the types of inventions that deserve a patent, including redefining what is novel and non-obvious?
- **Does the current standard for invention incentivize companies to extract as many patents as possible** on a single active substance in order to prolong the monopoly period?
- Should subsequent patents be considered inventive **if they cover subject matter that were already disclosed** in the first patents?
- **Does the current “drip feed” patent strategy represent a loophole** that is allowing drug makers to extend their monopoly protection?

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