Imbruvica's Patent Wall

Patent Search Methodology

The Orbit Intelligence patent database from Questel was used as the principal patent search reference. Exact compound structure searches were made using SciFinder. The United States Patent and Trademark's Pair database was also used to check the status of patent applications.

We conducted a comprehensive search to identify and analyze all patents in the United States related to the product Imbruvica (ibrutinib). This included identifying all patent applications (pending and abandoned) and granted patents (current and expired).

Patent families were identified and each individual patent application, whether abandoned, or re-filed as a continuation, continuation-in-part, or divisional application was counted as a distinct application. Once all relevant patents were identified, they were arranged in order of priority, filing, and expiry date.

Our legal and scientific team then reviewed each patent application and created groupings that paralleled other literature and analysis on patents.[1] As patents are made up of several claims, many patents had claims that could be placed into different categories. In these circumstances, the patent was classified by the main and broadest claim. When analysing each patent, an assessment was made as to the scope of protection sought by each patent and whether the patent related to the marketed form of Imbruvica.

Spending Forecast Methodology

We built a forecast to estimate total spending on Imbruvica during the nine-year period of extended exclusivity after the first set of patents expire, from 2027 to 2036. The forecast is based on actual net revenues received and reported by AbbVie and Johnson & Johnson (J&J), the companies with co-exclusivity rights to market and sell Imbruvica in the U.S. Revenue data reported in the annual 10-K reports of each company shows a combined $10.2 billion in net U.S. sales from inception to

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[1] T Amin and A Kesselheim. Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could be Extended for Decades. *Health Affairs*. Vol 31, No.10, 2012. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2012.0107

2018 (the most recently available). AbbVie's share was 2.5x that of J&J ($7.4B vs $2.9B) and the combined annual growth in spending was 36% for 2016 to 2017 and 37% for 2017 to 2018.[2]

To estimate future U.S. spending on Imbruvica, we extrapolated from these historical data in two approaches:

First, we anchored to a revenue estimate from Evaluate Pharma (May 2019) that forecast Imbruvica as the fourth highest grossing drug in 2024 with AbbVie's share of Imbruvica sales estimated to be $6.2B[3]. We forecast annual growth rates in total Imbruvica U.S. sales from 2019 to 2024 that most reasonably reached that figure based on historical actuals: 25% (2019), 20% (2020), 15% (2021), 10% (2022), 7% (2023), and 5% (2024). We assumed that AbbVie would keep the same 2.5-fold greater annual revenues as compared to J&J during the entire period.

Second, to project Imbruvica spending from 2025 to 2036, we modeled multiple scenarios with different annual revenue growth rates. Conservatively and for the sake of simplicity, we assumed constant growth rates in each of these twelve years for three different scenarios: -10%, -5% or 0% growth. The total estimated spending on Imbruvica from 2027-2036 was then calculated at: $41B (-10% annual growth), $57B (-5% annual growth), and $79B for 0% annual growth). In sum, our forecast estimates that total Imbruvica spending in the U.S. grows from $4.0B in 2018 to reach a peak of $8.7B in 2024 and then declines to $2.5B in 2036 (in the -10% scenario).

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[2] Imbruvica U.S. revenues were obtained from 10-K annual reports from AbbVie (https://investors.abbvie.com/static-files/71f9318f-9a32-42ee-92ee-a34975edcd19) and J&J (https://johnsonandjohnson.gcs-web.com/node/46106/html)

[3] World Preview 2019, Outlook to 2024. 12th edition. June 2019, p.24. https://info.evaluate.com/rs/607-YGS-364/images/EvaluatePharma_World_Preview_2019.pdf