How Have Manufacturers Relied on Device Patents to Preserve Market Exclusivity on Brand-name Inhalers?

STUDY DESIGN

- Conducted a review of patents on brand-named inhalers using the Food and Drug Administration's (FDA) orange book
- Information regarding patents extracted from LexisNexis TotalPatent One and Google Patents
- Determined duration of protection added by device patent for each inhaler

RESULTS

- The FDA approved 53 brand-name inhalers for asthma and COPD from 1986 through 2020, 39 of which had at least one device patent
- 77% did not mention active ingredients or their molecular structures
- Device patents extended periods of market exclusivity by a median of 5.5 years (25%-75% IQR, 0-10.5 years)

Patent and regulatory reform are needed to promote generic competition and to ensure that patients with asthma and COPD have access to affordable medications.