**PATENT VERSUS EXCLUSIVITY**

**Patents:** Granted by the US Patent and Trademark Office (or an analogous agency in another country). Patents generally last for 20 years.

**Exclusivity:** Granted by the FDA upon drug approval. Exclusive marketing rights, which range from six months to seven years, give a manufacturer sole promotion rights of a drug for a certain indication as an incentive for drug innovation and prevention of generic drug competition.

**Off-label drug use:** When a drug is used in a different disease, administered in a different way or at a different dose than what has been specified in the drug’s label (based on clinical trial data reviewed by the FDA for approval). Any drug on the market can be prescribed on an off-label basis at doctors’ discretion.