Improving Patent Practices for Biopharma to Increase Competition & Lower Drug Prices

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2 of the Policies Under Consideration by the USPTO to Improve Competition and Access to More Affordable Medicines

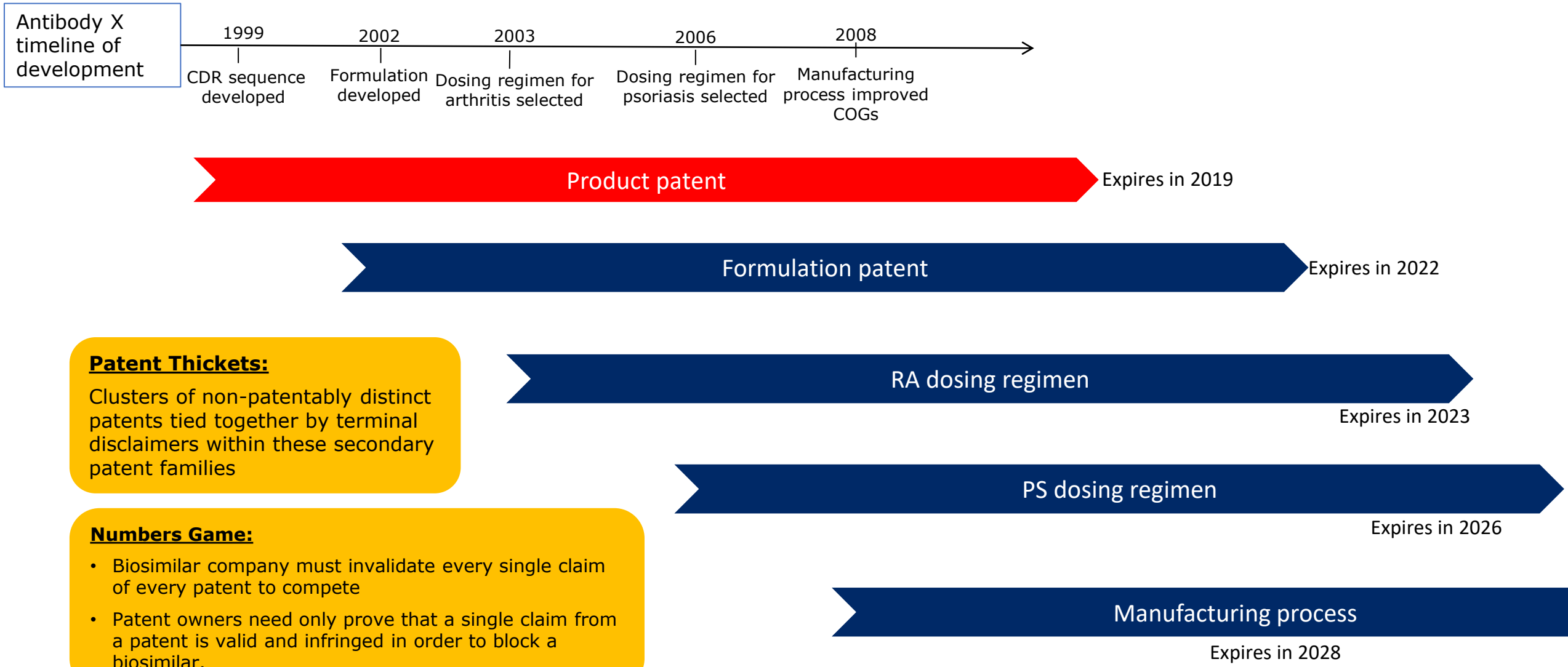
Request for Comment Question #7:

Currently, patents tied together with a terminal disclaimer after an obviousness-type double patent rejection must be separately challenged on validity grounds. However, if these patents are obvious variations of each other, should the filing of a terminal disclaimer be an admission of obviousness? And if so, would these patents, when their validity is challenged after issuance, stand and fall together?

USPTO/FDA Coordination:

How to enhance collaboration between the agencies to advance competition and access in the marketplace, while incentivizing and protecting innovation.

Patent Thickets Act as Barriers to Biosimilars Market Entry



Patent Thickets:

Clusters of non-patentably distinct patents tied together by terminal disclaimers within these secondary patent families

Numbers Game:

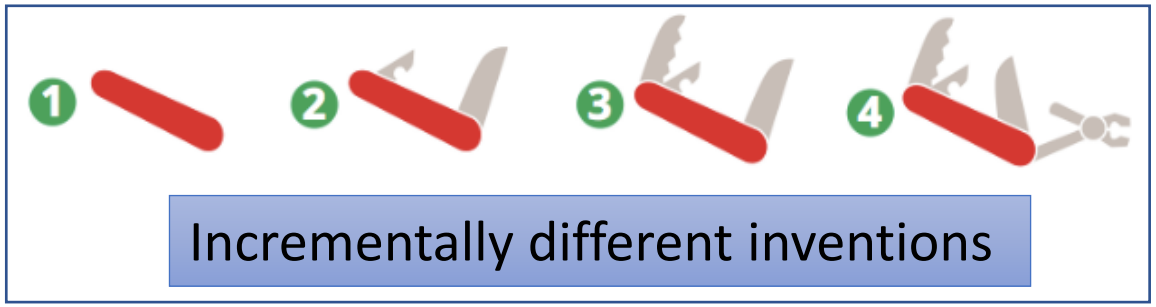
- Biosimilar company must invalidate every single claim of every patent to compete
- Patent owners need only prove that a single claim from a patent is valid and infringed in order to block a biosimilar.

Terminal Disclaimers contribute to Patent Thickets

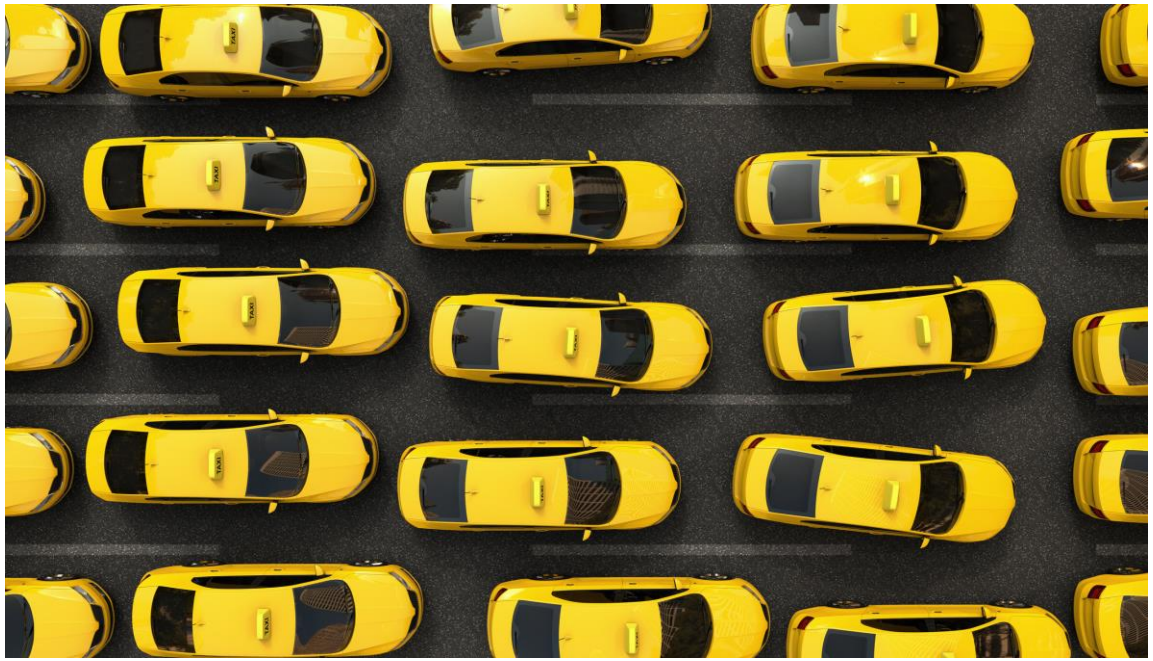
A patentee can overcome an "obviousness-type double patenting" challenge by filing a terminal disclaimer, which aligns the expiry date of the two, or more patents. This is supposed to ensure that patents claiming the same invention could not inappropriately extend the life of the original, or "parent patent".

In other words, **a patent owner may obtain multiple patents with non-patentably distinct claims**. This results in a cluster of patents, tied together by terminal disclaimers.

Peer reviewed data* shows that patent thickets are comprised <u>mostly</u> of non-patentably distinct inventions not incrementally different inventions



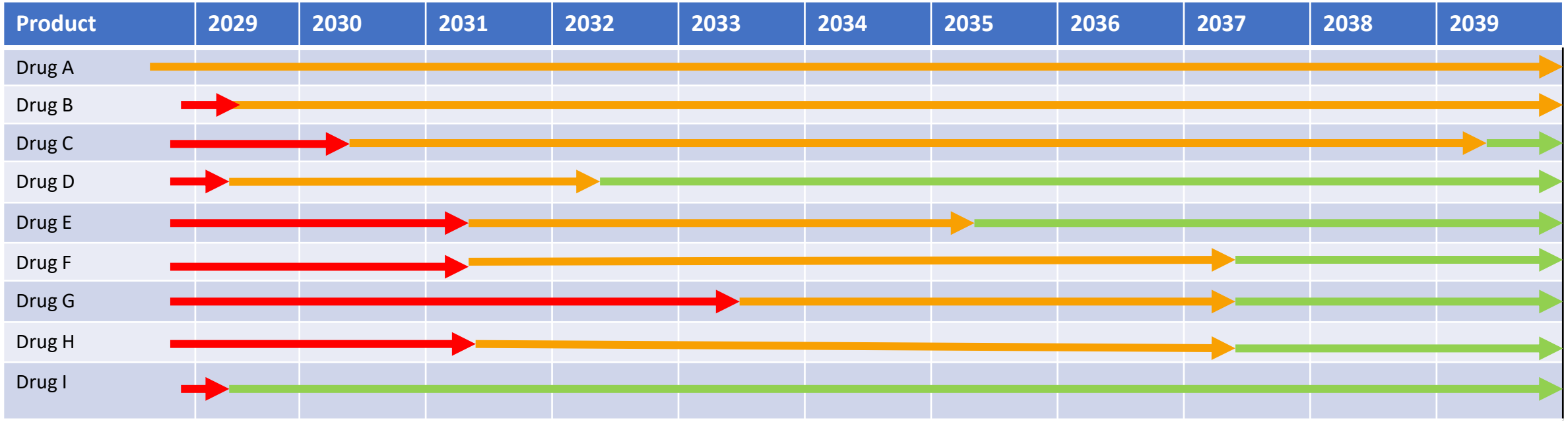
Incrementally different inventions



Non-patentably distinct inventions

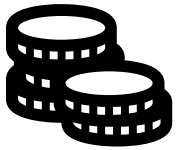
* https://academic.oup.com/jlb/article/9/2/lsac022/6680093

Patent estates of next generation biological blockbusters



- The red arrow shows the shows the expiry of the primary product patent on the drug product and the orange arrow shows the expiry of the last of the secondary patents.
- Brands use patent thickets as barriers to biosimilar market entry during the orange arrow time period

Why does it matter if there are high numbers of patents if the patents within a cluster expire at the same time?



High cost to Biosimilars

It is much cheaper to obtain a patent than to challenge a patent:

Approximately, $25,000 to obtain and maintain a patent

Approximately $1 million to challenge a biological patent via an IPR/PGR.

Biosimilar companies cannot economically use IPR/PGR to challenge scores of patents. Furthermore, it is unlikely that a federal court can effectively litigate scores of patents. **Therefore, large patent estates may enable shielding low-quality patents from scrutiny**

High risk & uncertainty to Biosimilars

"**Batting averages**": the biosimilar company must invalidate every claim of every patent in order to obtain freedom to operate whereas the patent owner need only prove that a single claim from a patent is valid and infringed in order to block a biosimilar.

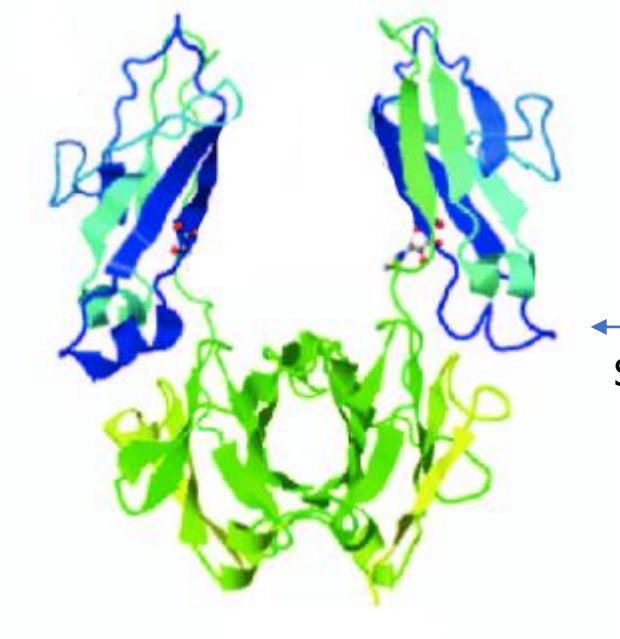
This problem is compounded by the increasing use of discretionary denials of IPR/PGRs.

Principal and Ancillary Product Patents

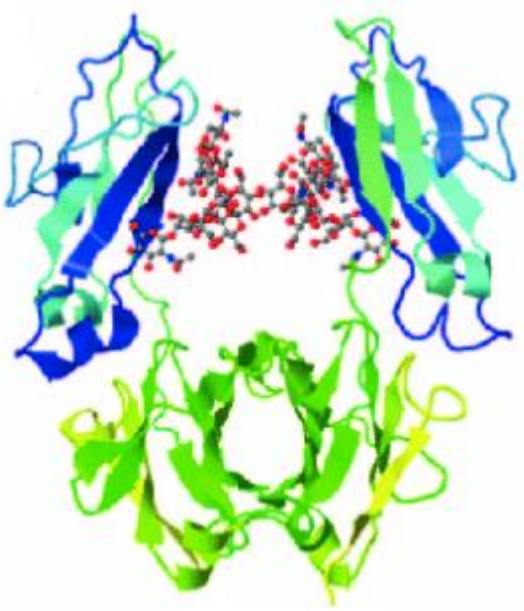
- In addition to building Patent Thickets, brands are also attempting to extend product patent protection for biologics by claiming specific technical features of the product (e.g. glycosylation, purity, etc.) in later filed applications

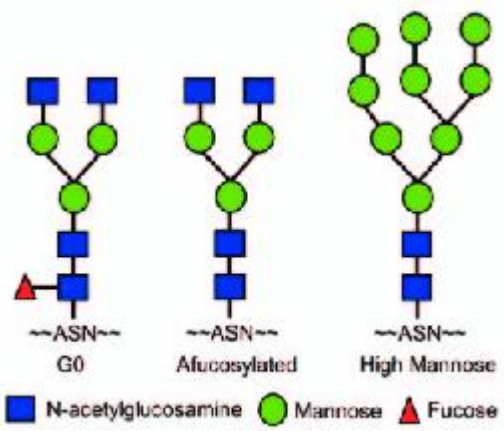
For Example:

2010 **2020**



Same Drug

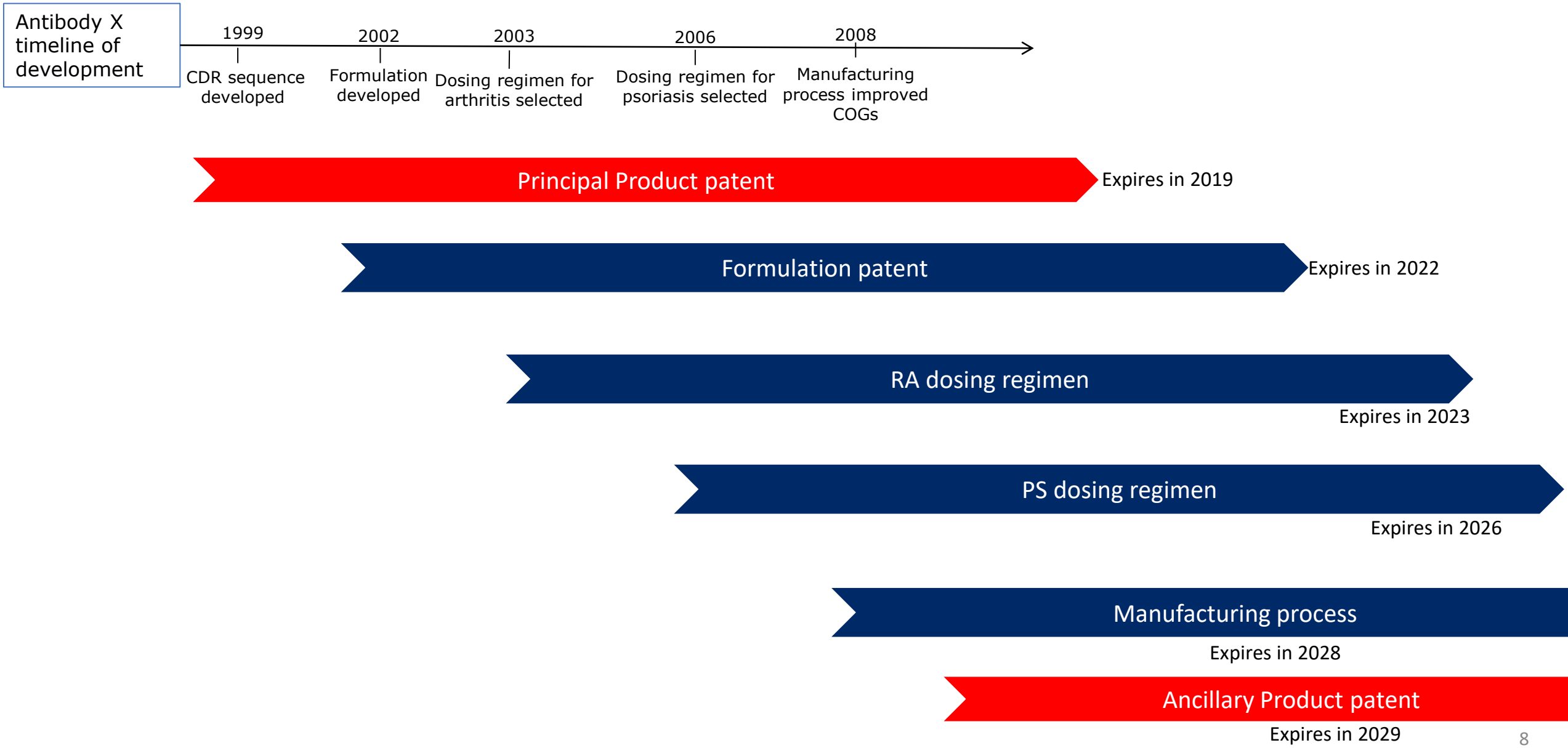




Principal Product Patent
Amino Acid Sequence

Ancillary Product Patent
Technical features on the Amino Acid

Ancillary Product Patents



FDA/USPTO Coordination Will Reduce the Gamesmanship of Ancillary Product Patents

- When pursuing this strategy, the patent owner necessarily holds back information about the technical features of the drug's structure when first filing the principal product patent
- But they are **required** to disclose these same technical features about the drug to the FDA when seeking approval for the drug
- Because the information that is disclosed to the FDA for drug approval is confidential, it is not available to patent examiners and prevents them from determining whether it is prior art to the ancillary product claims that are under examination

The FDA could collaborate with the Examiner by:

- answering specific questions regarding the technical details of the approved product that is the subject of patent examination;
- providing FDA guidance documents that can serve as prior art (e.g., requirements for certain technical structures, drug purity etc);
- providing relevant extracts from the drug regulatory dossier