Intersectionality of Intellectual Property with Licensing and Commercialization

LSPN Fall 2024

Jason Murata (jmurata@axinn.com) | Axinn, Veltrop & Harkrider LLP

Michael Davitz (davitz@leasonellis.com) | Leason Ellis LLP

Danielle Burns (danielle.burns@pof.com.au) | Phillips Ormonde Fitzpatrick

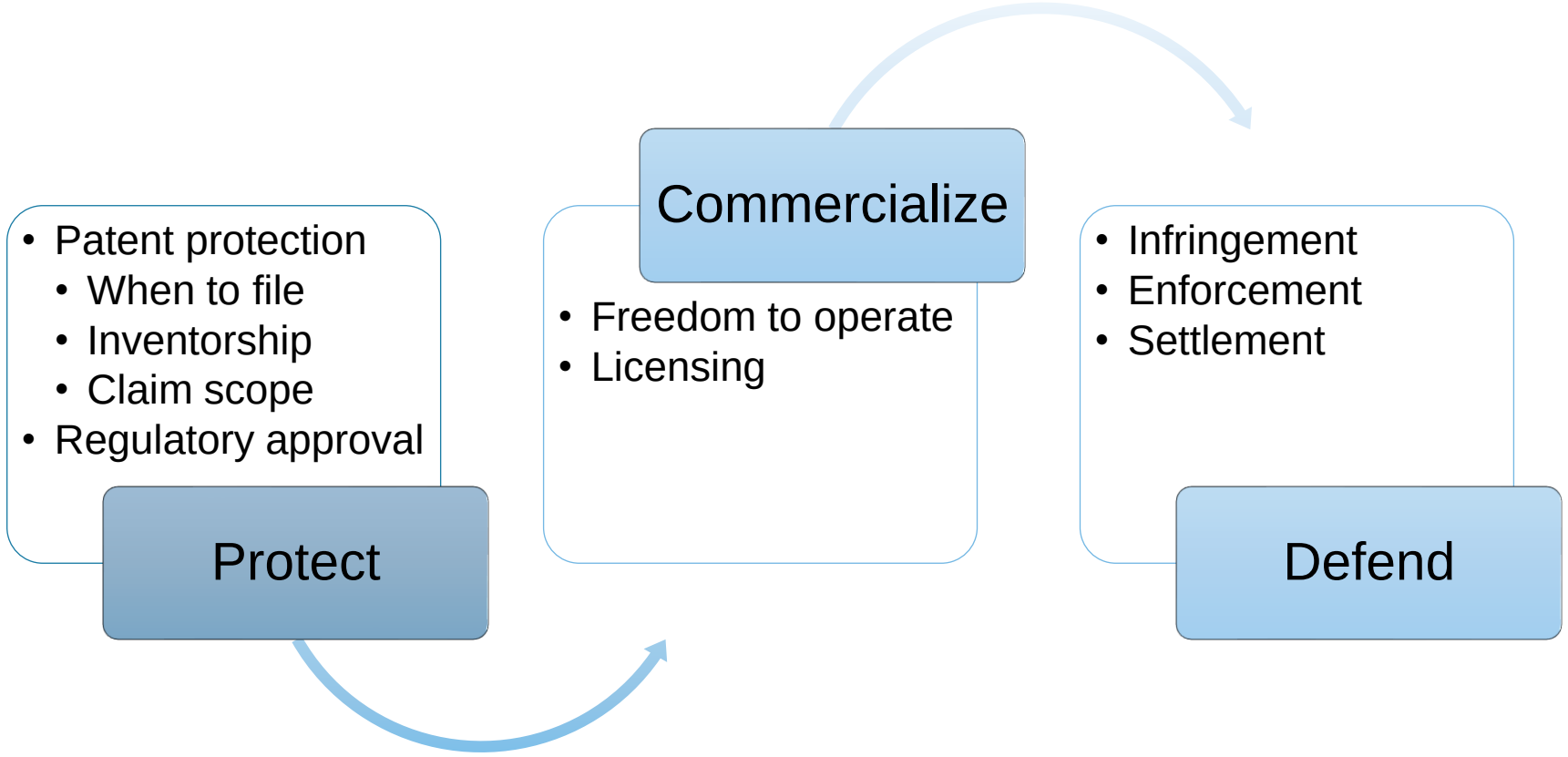
David Lngmuir (david.longmuir@pof.com.au) | Phillips Ormonde Fitzpatrick

phillips ormonde fitzpatrick
the IP protection people

15 October 2024

Patent Power Play: Protect, Profit, and Prevail!

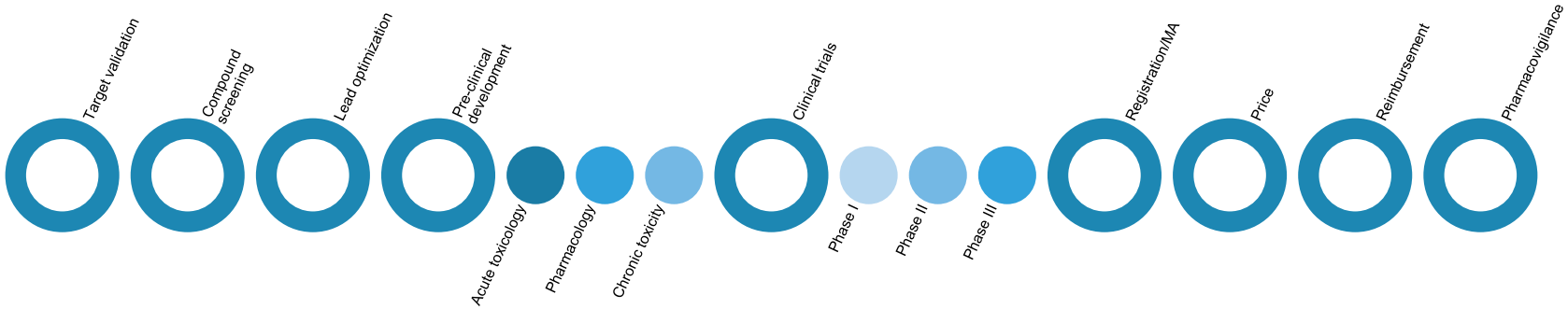
Maximizing patent value at every stage

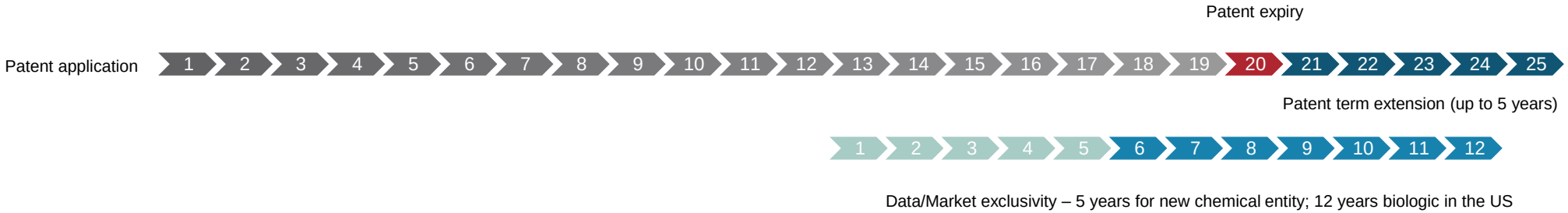


 15 October 2024

Maximizing Value

From early stages of research





 15 October 2024

When to file

CRISPR-Cas9 litigation

12 Dec 2012

Broad group

First patent application protecting use of CRISPR technology in eukaryotes

11 Jan 2016

CVC/Broad

Interference No. 106,048

USPTO announces interference proceedings to determine whether Broad's patents interfere with CVC's patent application

US PTAB ruled that there was no interference in fact between Broad's claims to methods of performing CRISPR-mediated DNA cleavage in eukaryotic cells and CVC's claims for CRISPR methods not limited to cell type (Feb 2017)

25 Jul 2017

CVC appalled PTAB decision to the US Court of Appeals for the Federal Circuit. Ruled in favour of Broad

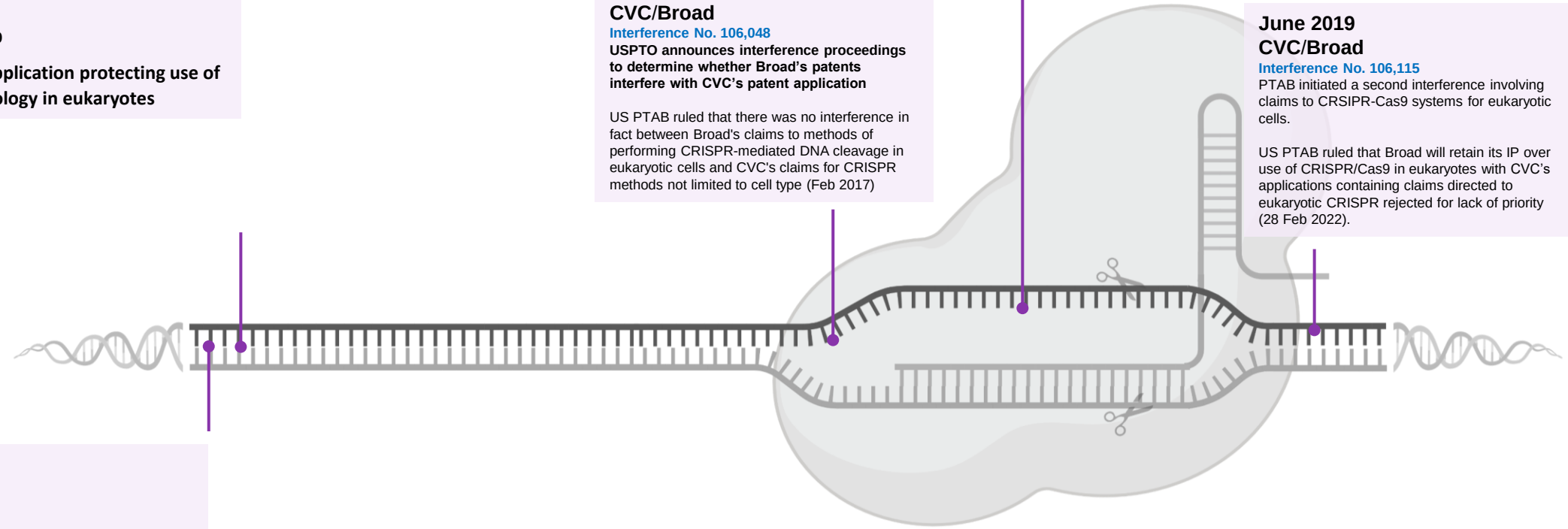
June 2019

CVC/Broad

Interference No. 106,115

PTAB initiated a second interference involving claims to CRSIPR-Cas9 systems for eukaryotic cells.

US PTAB ruled that Broad will retain its IP over use of CRISPR/Cas9 in eukaryotes with CVC's applications containing claims directed to eukaryotic CRISPR rejected for lack of priority (28 Feb 2022).



25 May 2012

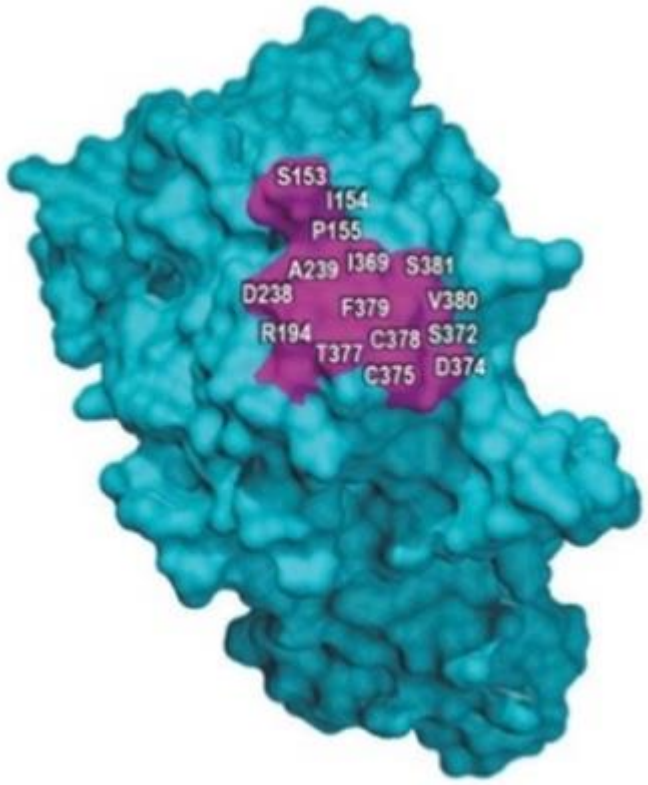
CVC group

First patent application protecting the CRISPR-Cas9 gene editing tool

 15 October 2024

Balance being first to file with having adequate patent support

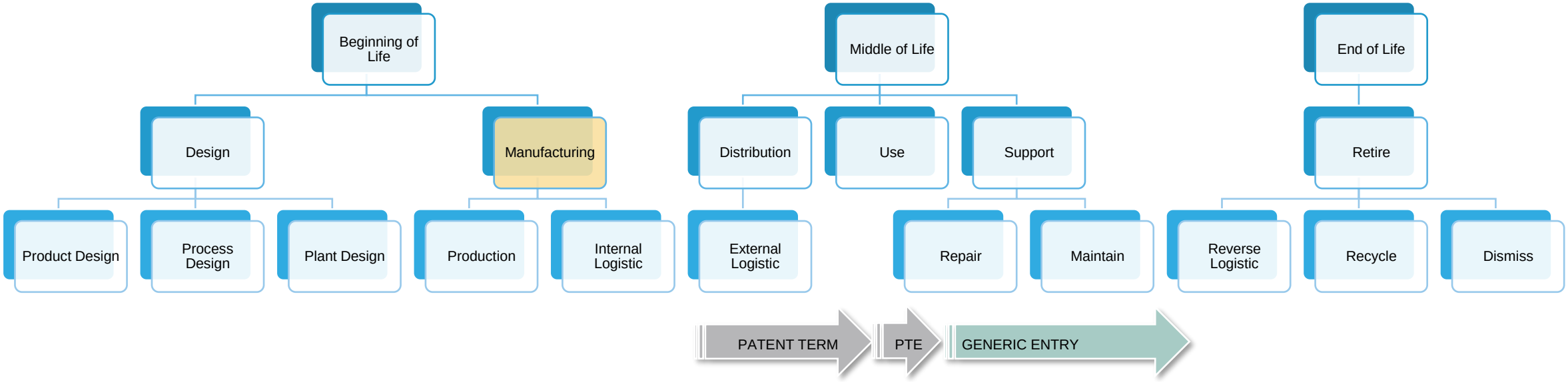
anti-PCSK9 litigation



- 3000 antibodies were screened to determine if they block binding of PCSK9 to LDL receptor → 300 did "well", 100 blocked >90%
- 26 actual antibodies made and sequenced; detailed characterization of two specific antibodies, 31H4 and 21B12.
- Two antibodies identified as binding to a specific region of PCSK9 (31H4 and 21B12)
- Crystal structure of the PCSK9-LDL receptor complex → identifies amino acid residues at the interaction interface
- Crystal structures of PCSK9 bound to 31H4 and 21B12 → identifies amino acid residues proximate to binding

Product lifecycle

Manufacturing considerations



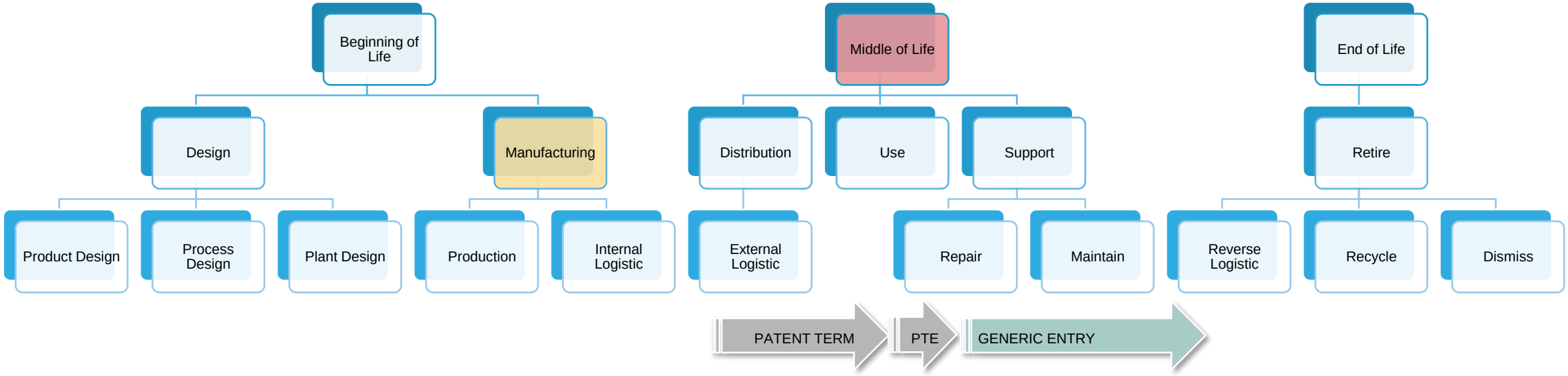
Adapted from : Duque Ciceri, N., Garetti, M., & Terzi, S. (2009). Product lifecycle management approach for sustainability. In Proceedings of the 19th CIRP Design Conference–Competitive Design. Cranfield University Press.

 15 October 2024

Why is an antibody like a cell phone?

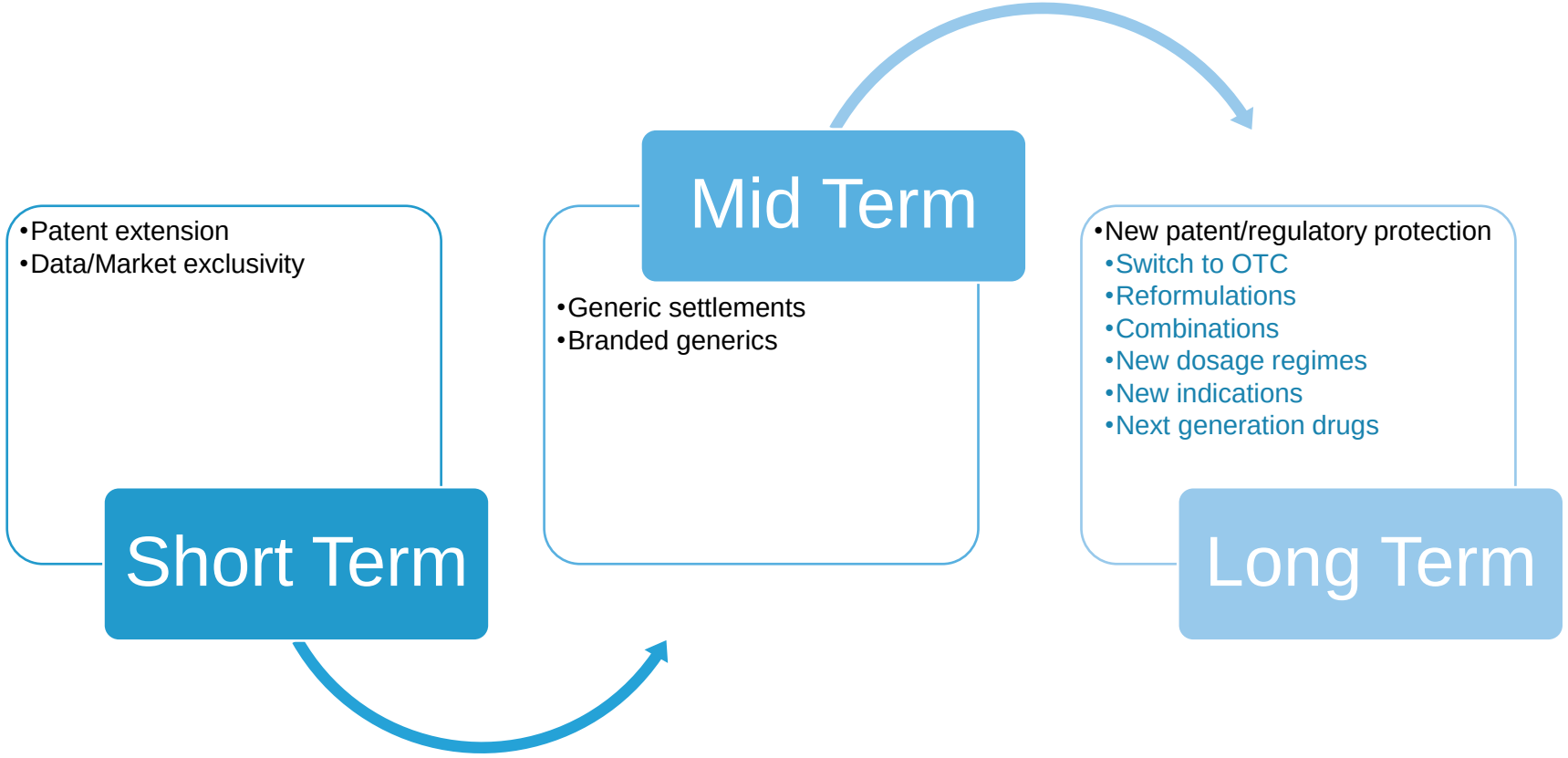
Product lifecycle

Middle of life



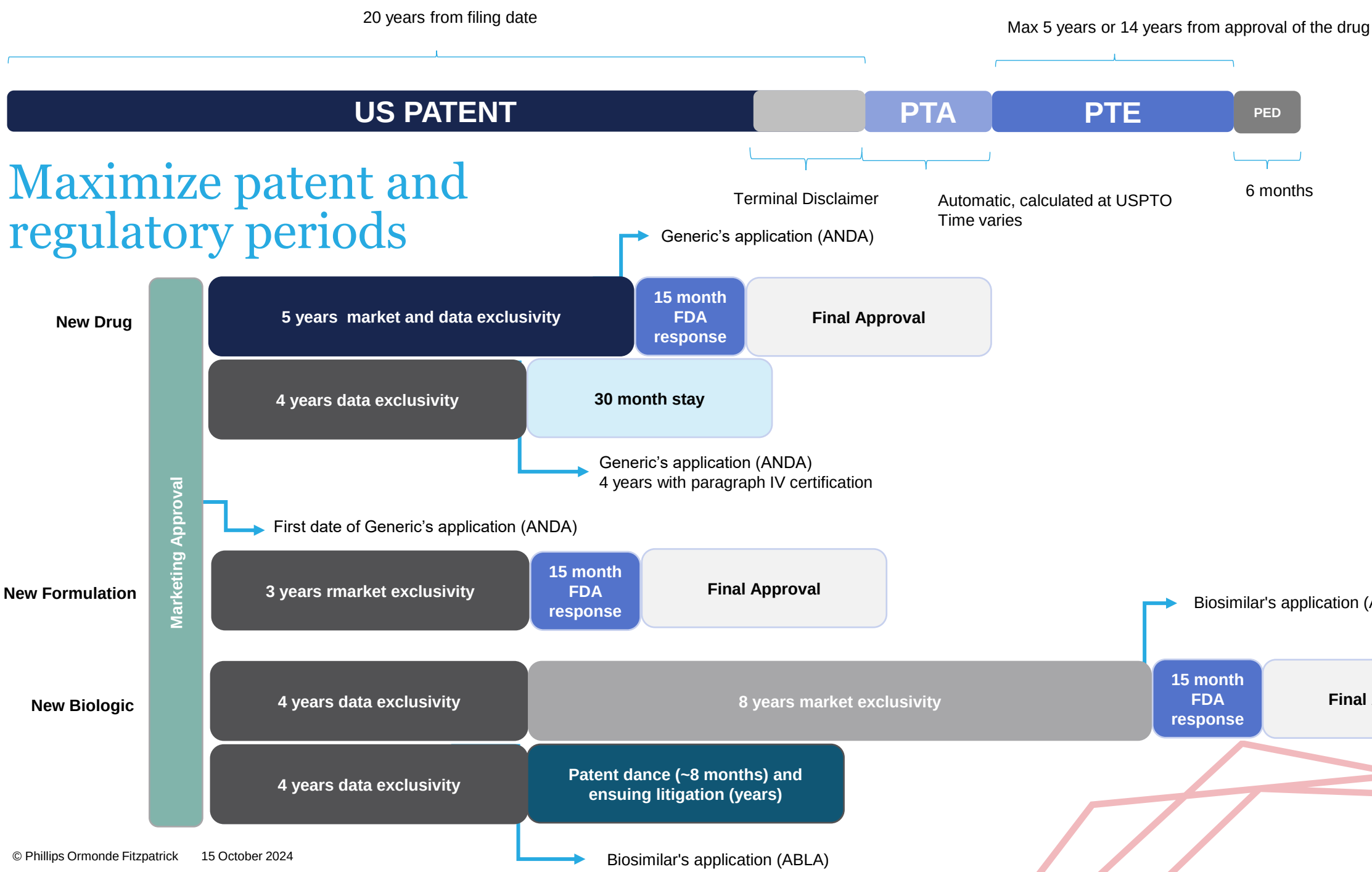
Adapted from : Duque Ciceri, N., Garetti, M., & Terzi, S. (2009). Product lifecycle management approach for sustainability. In Proceedings of the 19th CIRP Design Conference–Competitive Design. Cranfield University Press.

Extending mid-life of your drug – so that it never turns 40!



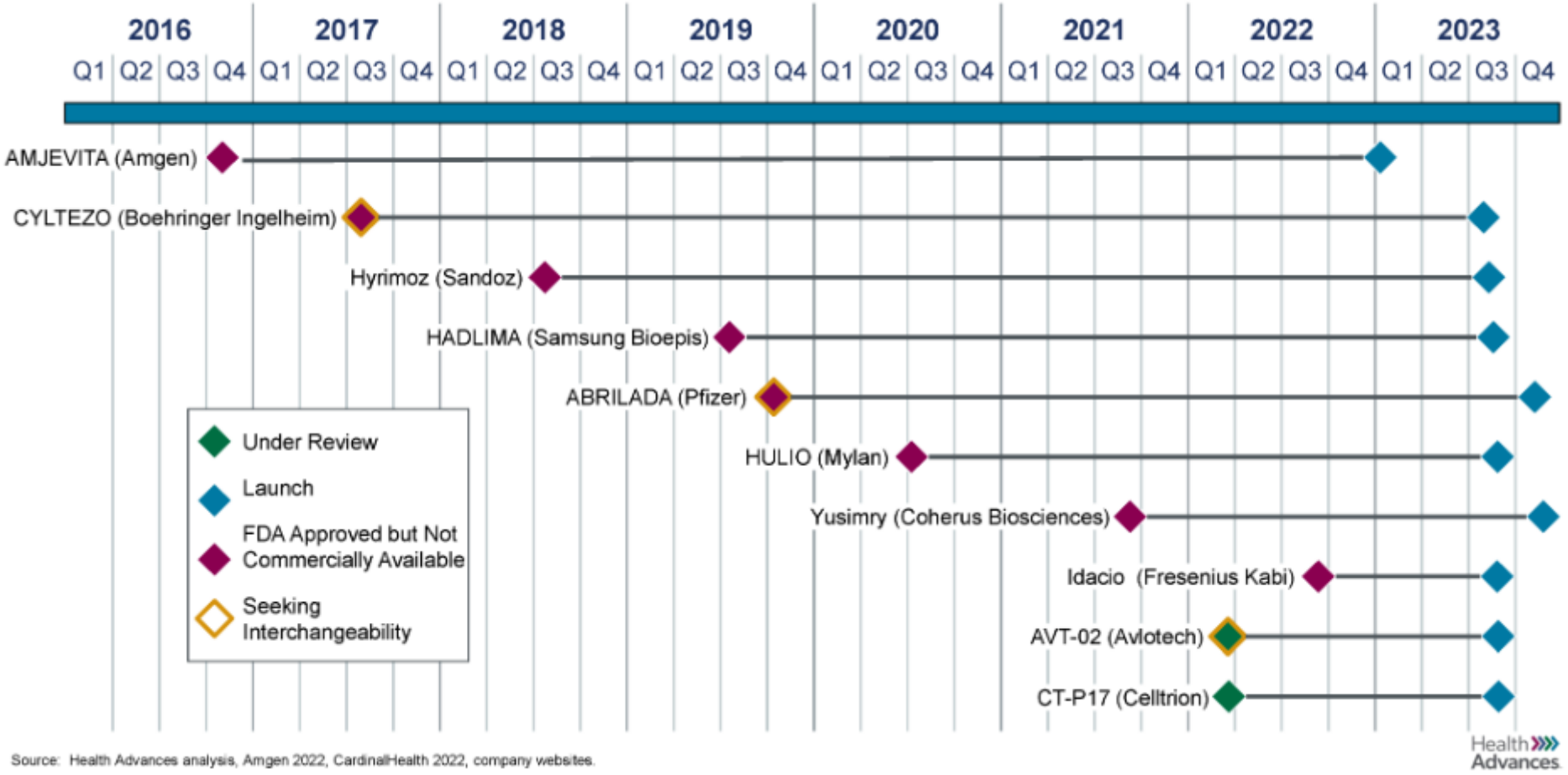
 15 October 2024

Maximize patent and regulatory periods



Generic settlements

Humira



Key takeaways

- Early and strategic filing
- Comprehensive patent thicket
- Leverage PTE and data/exclusivity periods
- Global patent strategy
- Monitor and adapt to market changes
- Explore partnerships and licensing agreements early in manufacture design
- Proactive lifecycle management

