

Exclusivity for Biologics & Pharmaceuticals

David Ridley

Duke University

November 2013



@dave_ridley

Encouraging Innovation

- Monopoly power from government
 - Patent
 - Exclusivity
- Monopoly power from differentiation
 - Brand
 - First mover
 - Specialized skills
- Prizes from government or foundations
 - priority review voucher
- Research subsidies from government or foundations

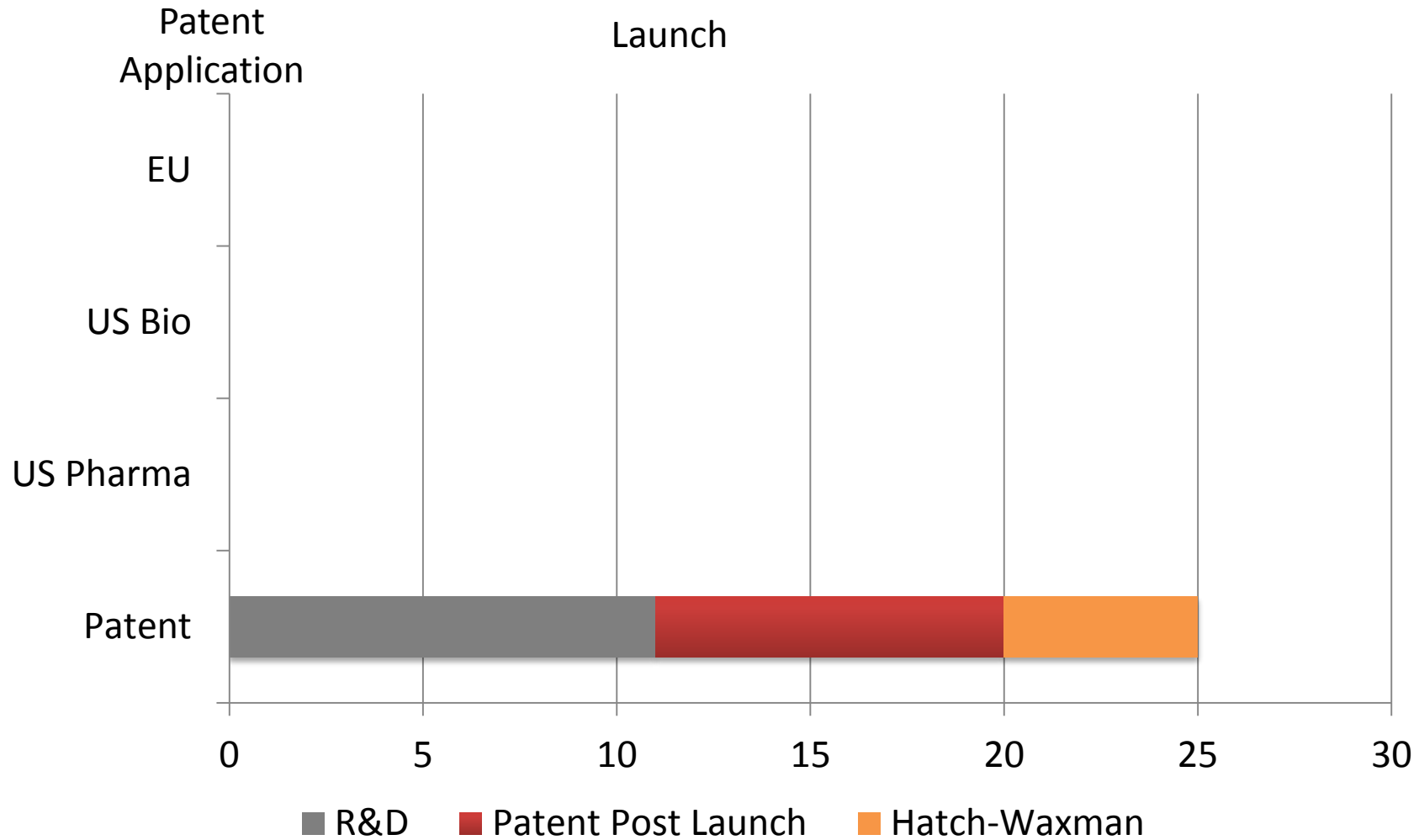
Encouraging Innovation

- Monopoly power from government
 - Patent
 - Exclusivity
 - Monopoly power from differentiation
 - Brand
 - First mover
 - Specialized skills
- Prizes from government or foundations
 - priority review voucher
 - Research subsidies from government or foundations

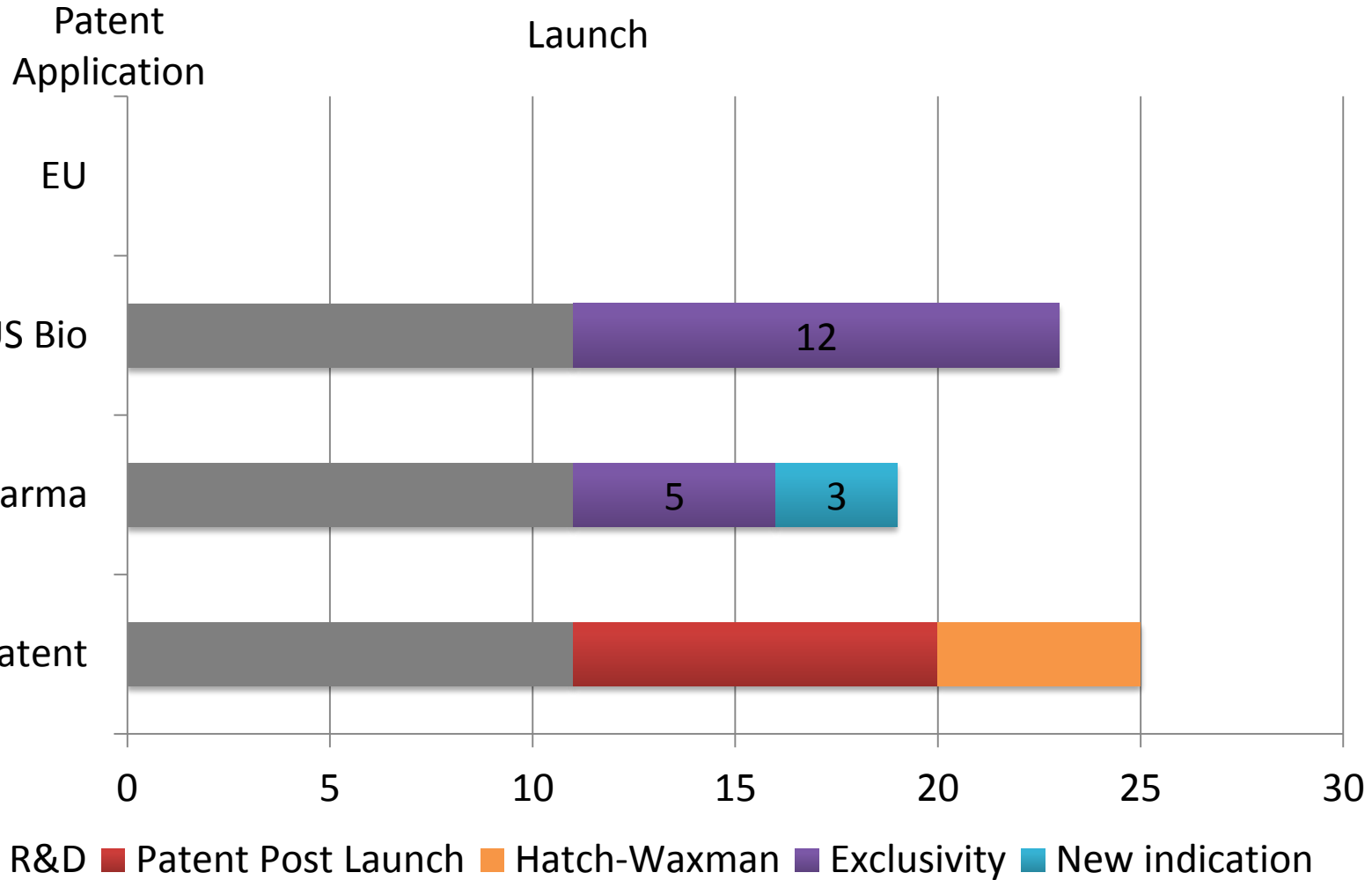
Encouraging Innovation

- Monopoly power from government
 - Patent
 - Exclusivity
- Monopoly power from differentiation
 - Brand
 - First mover
 - Specialized skills
- Prizes from government or foundations
 - priority review voucher
- Research subsidies from government or foundations

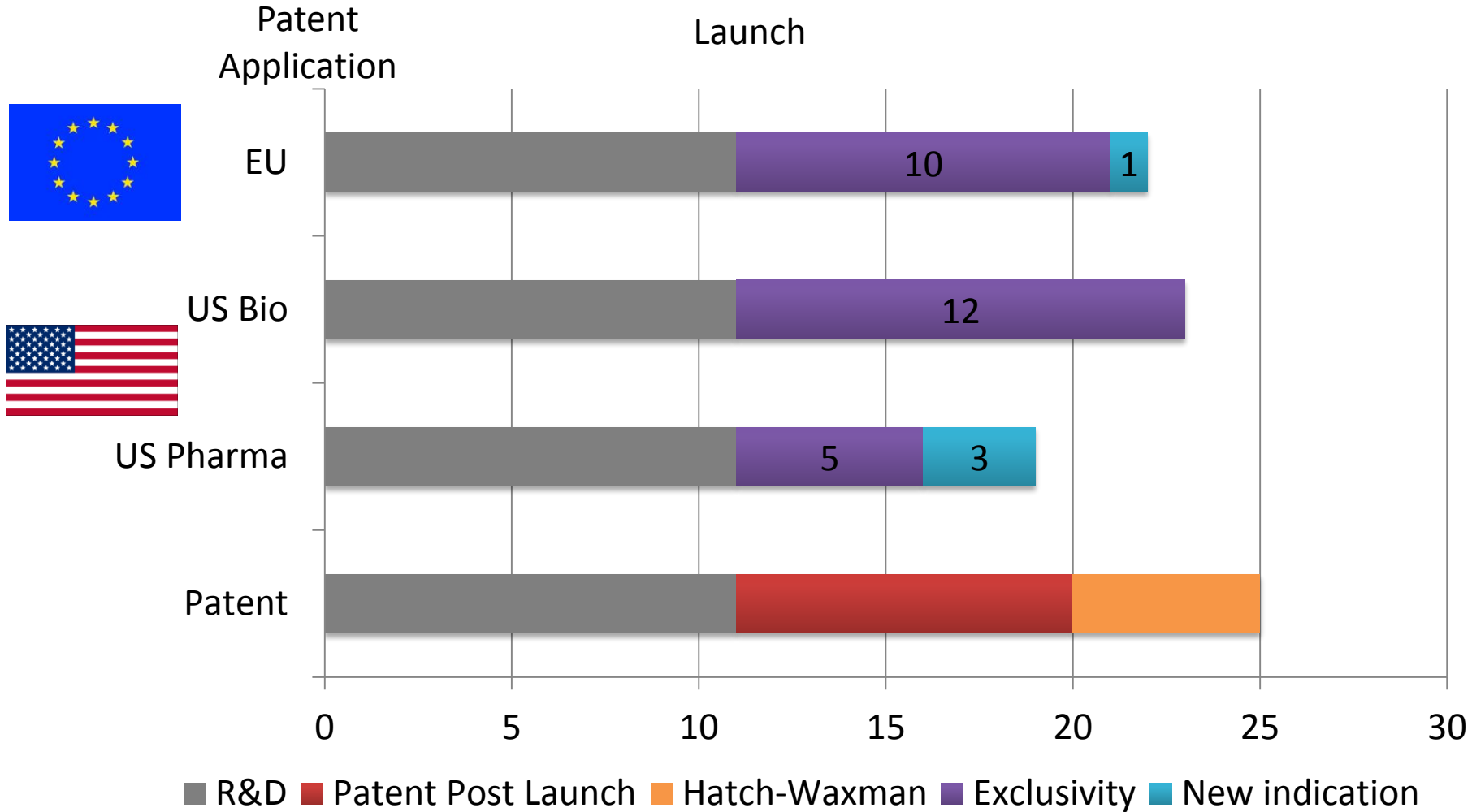
Patents and Exclusivity



Patents and Exclusivity



Patents and Exclusivity



Data Exclusivity



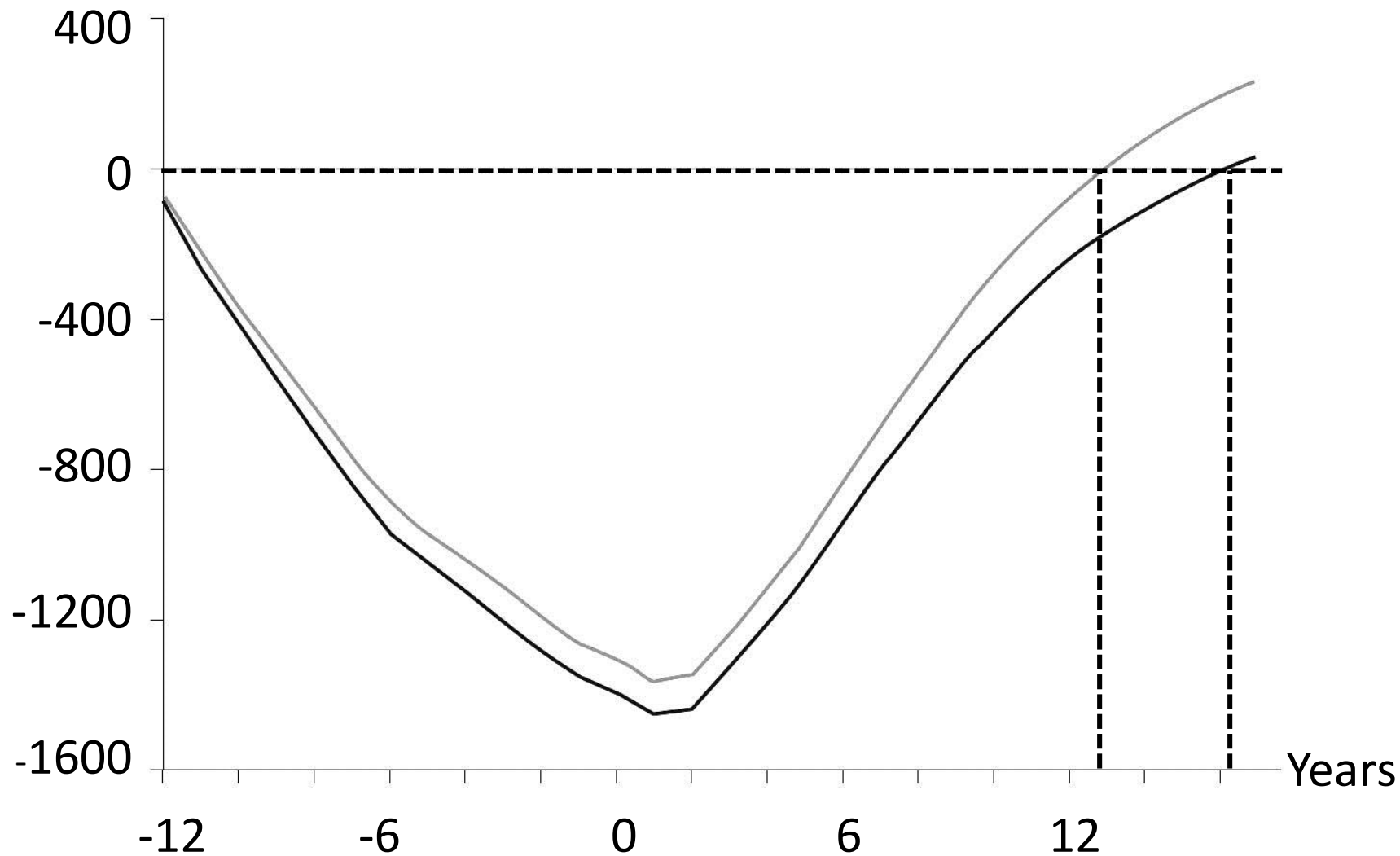
$10+1$	$5+3$
$10+1$	12

Cumulative
net present
value (\$M)

For discount rate 11.5%, 12.9 years

For discount rate 12.5%, 16.2 years

Source: Grabowski, Nature Reviews DD, 2008



If decrease exclusivity for biologics

- Earlier access to biosimilars
- But biosimilars might not decrease spending
- But with insurance less deadweight loss

If decrease exclusivity for biologics

- Assuming exclusivity (not patent) binds
- Lose marginal drugs:
 - Lower value per patient
 - Fewer patients (orphan)
 - Lower probability of success
 - Longer trials

If *increase* exclusivity for *pharma*

- Assuming exclusivity (not patent) binds
- Gain marginal drugs:
 - Lower value per patient
 - Fewer patients (orphan)
 - Lower probability of success
 - Longer trials

Data Exclusivity



$10+1$	←	$5+3$
$10+1$	←	12

Conclusions

- Exclusivity
 - Alternative to patents
 - Reward new research on old drugs
- Harmonize
 - Why different bio versus pharma?
 - If biologic exclusivity shorter, then speed biosimilars