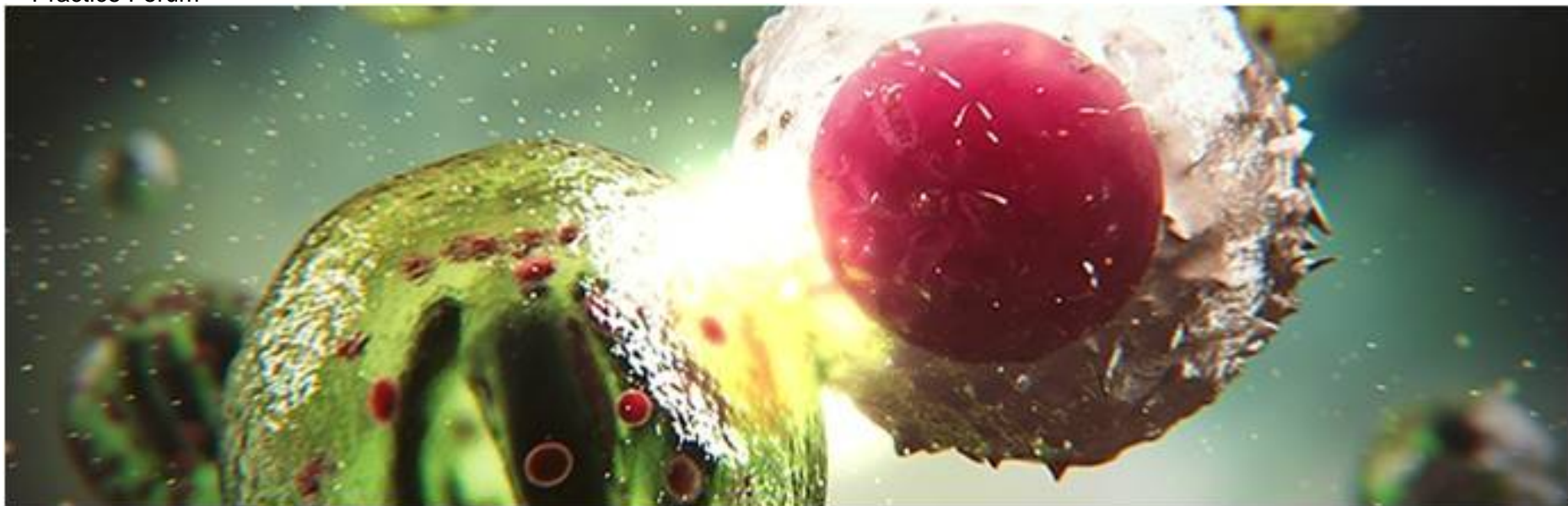


# MINI SUMMIT III: COMPETITION/ANTITRUST LAW UPDATE

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International Pharmaceutical Compliance Congress and Best  
Practice Forum

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# Recent Developments



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- Denigration
- Collaboration Agreements
- Pricing strategies
- Others?



# Denigration

- Number of French cases: Sanofi (*Plavix*), Schering Plough (*Subutex*)
- Key Principle - putting into question the safety, efficacy or quality of competitor/generics, as part of a marketing strategy aimed at doctors and other health care professionals.
- In practice:
  - Focus on quality of own product
  - Highlight objective meaningful differences, scientific evidence?
  - Tell the whole story



# Collaboration Agreements

- Recent cases: Roche/Novartis (*Avastin/Lucentis*); J&J/Sandoz (*fentanyl*)  
Schering Plough/Reckitts (*Subutex*)
- Key Principle: Agreements should fall within a block exemption (new TTBER, other?), if not, consider 101(3) arguments. Must remember independent parties outside collaboration so avoid collusion within it.
- In Practice:
  - Provide advice early
  - Understand what it is the business is trying to achieve, legitimate business goal?
  - Think literally and laterally
  - Provide clear guidelines on what can/cannot be done during the collaboration



# Pricing Strategies

- Pricing Strategies: Napp (UK); Pfizer (Australia); Aspen (Italy); Proctor & Gamble (Greece)
- Key Principles: Following Intel and the removal of the recoupment test, the increasingly narrow market definition in pharma means that greater care needs to be taken with discount and pricing strategies
- In practice:
  - Market definition may change during life of product e.g. coming up to LoE so regularly review strategies
  - Business to get competition law advice in certain situations – set up flags
  - Consider internal monitoring & auditing?



# Others?

- Product Hopping
- Withdrawal
- Abuse of regulatory procedures
- Global developments



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