Agenda

1. How big is the patent barrier to biosimilar market entry in Europe?
2. Validity issues for biologic patents litigated in the UK
3. Are patent enforcement considerations different against biosimilars?
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1. How big is the patent barrier to biosimilar market entry in Europe?

• How big?
What do we know?

- FACT: there are 17 biosimilars approved by the EMA
- FACT: there has been very little biosimilar patent litigation
- FACT: we are approaching a biologic patent cliff
What don’t we know?

• Reasons why there is not much litigation
  - Not enough approvals to create the litigation?
  - Longer regulatory process and regulatory data protection issues?
  - Licensing?
  - Are biosimilars proceeding cautiously?
  - Waiting for patent expiry?
“Rapid access to the market on patent expiry is not a phenomenon that has yet been seen in the context of biosimilars…

… to date, patents and SPCs have been of less importance – in terms of barriers to entry for competitive products – than the strictures imposed by the regulatory framework”

Extending Rewards for Innovative Drug Development – A report on Supplementary Protection Certificates for the Intellectual Property Institute, August 2007
“In a large molecule context, due to the fact that risk is allocated symmetrically amongst large molecule innovators and challengers, with imposing R&D, manufacturing, and marketing costs on both sides, the innovator is now incentivized to litigate based on the validity of its actual patents and test the risk tolerance of its challengers.

As a result, we may experience far less settlements and more successful litigation pursuits by innovators, thereby creating an additional barrier to biosimilar entry.”

The Follow-On Biologics Market: Enter At Your Own Risk
Deloitte, 2011
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2. Validity issues for biologic patents litigated in the UK

- **Sufficiency**:
  - Classical insufficiency
  - Insufficiency by ambiguity
    - *Biogen* insufficiency

- **Plausibility**: Post-published evidence?

- **Technical contribution**:
  - Industrial applicability
  - Inventive step
2. Validity issues for biologic patents litigated in the UK

- **Information**
  - Post-published evidence?
  - **Sufficiency**
    - Classical insufficiency
      - *Lilly v Janssen* (CA)
    - Insufficiency by ambiguity
      - *Regeneron v Genentech*
        - Biogen insufficiency
      - *Lilly v Janssen*
  - **Plausibility**
    - *Hospira v Genentech*
    - *Mylan v Yeda*
      - Technical contribution
        - Industrial applicability
          - *Lilly v HGS* (SC)
        - Inventive step
          - *Mylan v Yeda*
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- *American Cyanamid* and the classic small molecule scenario

- 3 part test to obtain a preliminary injunction:
  
  i. Is there a serious question to be tried?
  
  ii. Are damages an adequate remedy?
  
  iii. Where does the balance of convenience lie?

- Many generics = greater threat:

  "[Mr Waugh QC] submitted that if Apotex were free to market their product, then others would follow. The result would be aggressive competition leading to a downward price spiral, a lower drug tariff price and very substantial damage to SB. The price could thereafter never be restored with dire consequences for SB".

  *SmithKline Beecham v Apotex*, Court of Appeal, 2003
3. Are enforcement considerations different against biosimilars?

- What if there is only one competitor and no prospect of more - can a preliminary injunction be obtained with a stable duopoly not a price spiral?
- Maybe – but more difficult. Leo Pharma succeeded in *Leo v Sandoz*:

  """Leo did not dissent from the fact, that, since there is only one competing product on the market, the price spiral that so often takes place when there are two or more generics coming into a patented field is unlikely to happen."

  ...

  [Nevertheless] The real point is that Leo currently have a monopoly price. If Sandoz come in with their considerable marketing powers, as a substantial company, and were to lower their price, the consequences of working out the financial damage to Leo go beyond merely difficult to being incalculable."

  *Lord Justice Jacob, Court of Appeal, 2008*
3. Are enforcement considerations different against biosimilars?

• But are there other reasons why the harm to the originator product is not irreparable?

• In particular, biosimilars are not substitutable in most European states so will the originator really need to lower its price to compete?

• Are there other reasons that would discourage switching (e.g. patient care programmes)?
Thank you for your attention

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