Challenges and opportunities for biosimilar patent litigation

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This presentation is...

» **NOT** about the regulatory pathways of biosimilars,

» **NOT** an exhaustive course in litigation strategies,

» **NOT** (necessarily) the view of (clients of) Crowell & Moring,

» But, a synthesis of «*Biosimilars and Belgian Patent Disputes (as) in summary proceedings: « To judge, one must understand ».*»

*(IRDI 2013/3)*
Why the article?

» **Genuine concern**
  
  » Small molecules are so 20th century
  
  » Biosimilars are complex
  
  » Production of biosimilars is complex and very expensive
  
  » Conclusion: biosimilars are NOT generics

» **And some frustration**
  
  » Prevailing case law on preliminary injunction in several European jurisdictions, in particular in Belgium
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Aspirin vs. monoclonal antibody. Source: J. Macdonald, Introduction to Biosimilars: From R & D to Product Registration
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Why the article? (2)

» EP’s are not necessarily *prima facie* valid
  » The EPO examiner is not infallible
  » EPO opposition proceedings can be relevant
  » Foreign case law can be relevant

» Biosimilars do not necessarily *prima facie* infringe
  » Make (some) room for a debate on (non-)infringement
  » No *per se* infringement

» Balance the interests at stake
Proposal

Preliminary rule in favor of biosimilar producer / distributor if:

- It is obvious for a skilled person that a mistake was made at EPO
- Certain elements/state of the art were not mentioned to / missed by EPO
- OD revokes the patent, in particular if original examiner is on panel
- TBA revokes the patent
- A foreign court has ruled that there is no valid patent / no infringement
- Patentee needs to argue infringement by way of equivalent
- There is a considerable ‘extra partes’ benefit from availability biosimilar
- If the hypothetical future damage of the patentee can be remedied by the biosimilar producer / distributor.
Required?

» Educate (PI) judges on biosimilars vs. generics
» Inform (PI) judges on the (social) impact of their decisions
» Explain (PI) judges that generics case law cannot be recycled

« To judge, one must understand »

LUCIUS ANNAEUS SENECA
Questions?

Now

or

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