

# **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

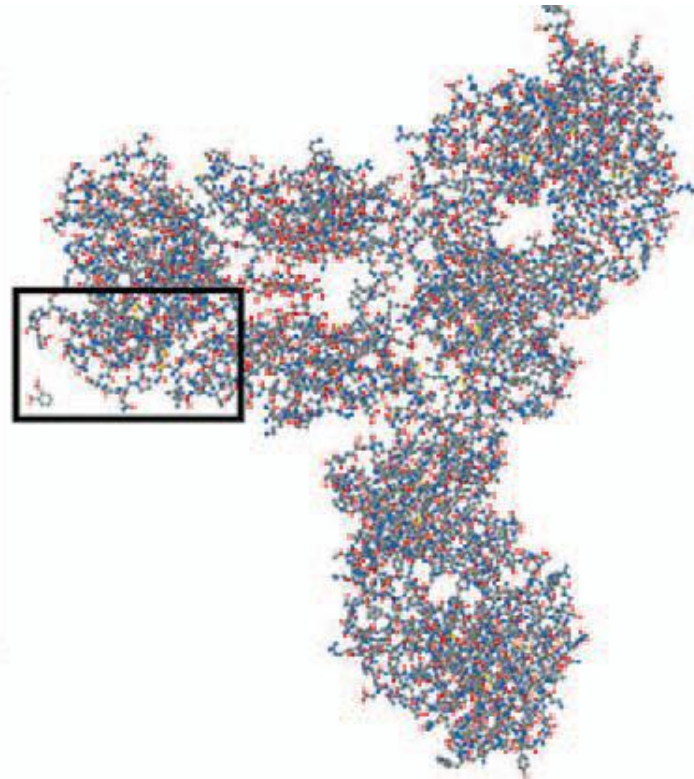
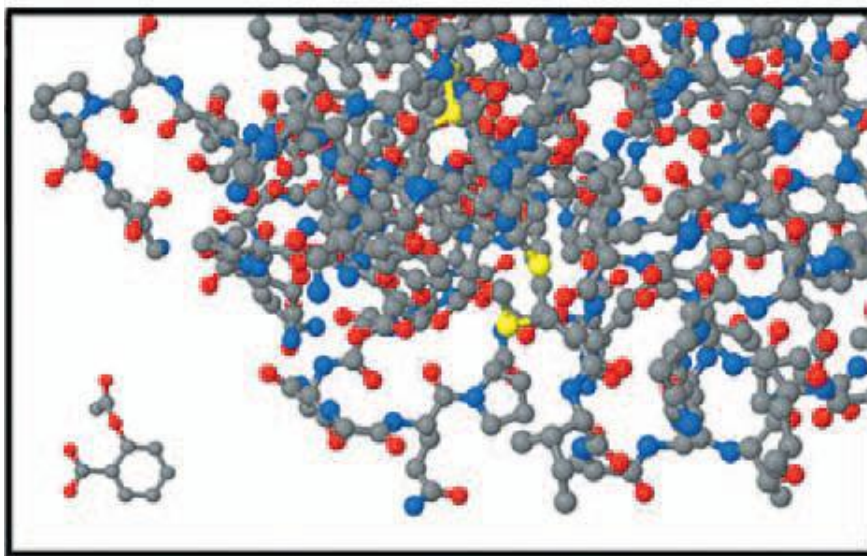
- » Small molecules are so 20th century
- » Biosimilars are complex
- » Production of biosimilars is complex and very expensive
- » Conclusion: biosimilars are NOT generics

## » And some frustration

- » Prevailing case law on preliminary injunction in several European jurisdictions, in particular in Belgium

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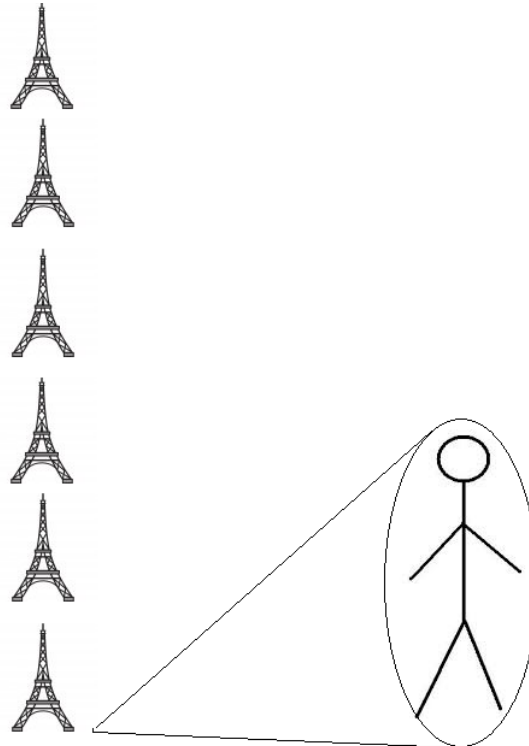
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Aspirin vs. monoclonal antibody. Source: J. Macdonald,<sup>4</sup> Introduction to Biosimilars: From R & D to Product Registration

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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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