Biosimilar Litigation Strategies

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WHAT IS A BIOSIMILAR?

- By **biosimilar** medicine we refer to a medicinal product that contains a version of the active substance of an already authorised biological medicinal product (reference medicine), which has been proved to be highly similar in terms of quality, safety and efficacy.
- A **biological medicinal product** is a product, the active substance of which is a biological substance.
- A biological substance is a substance that is produced by or extracted from a biological source, such as:
  - micro-organisms,
  - cells or fluids (including blood or plasma) of human or animal origin,
  - organs and tissues of either plant or animal origin,
  - biotechnological cell constructs

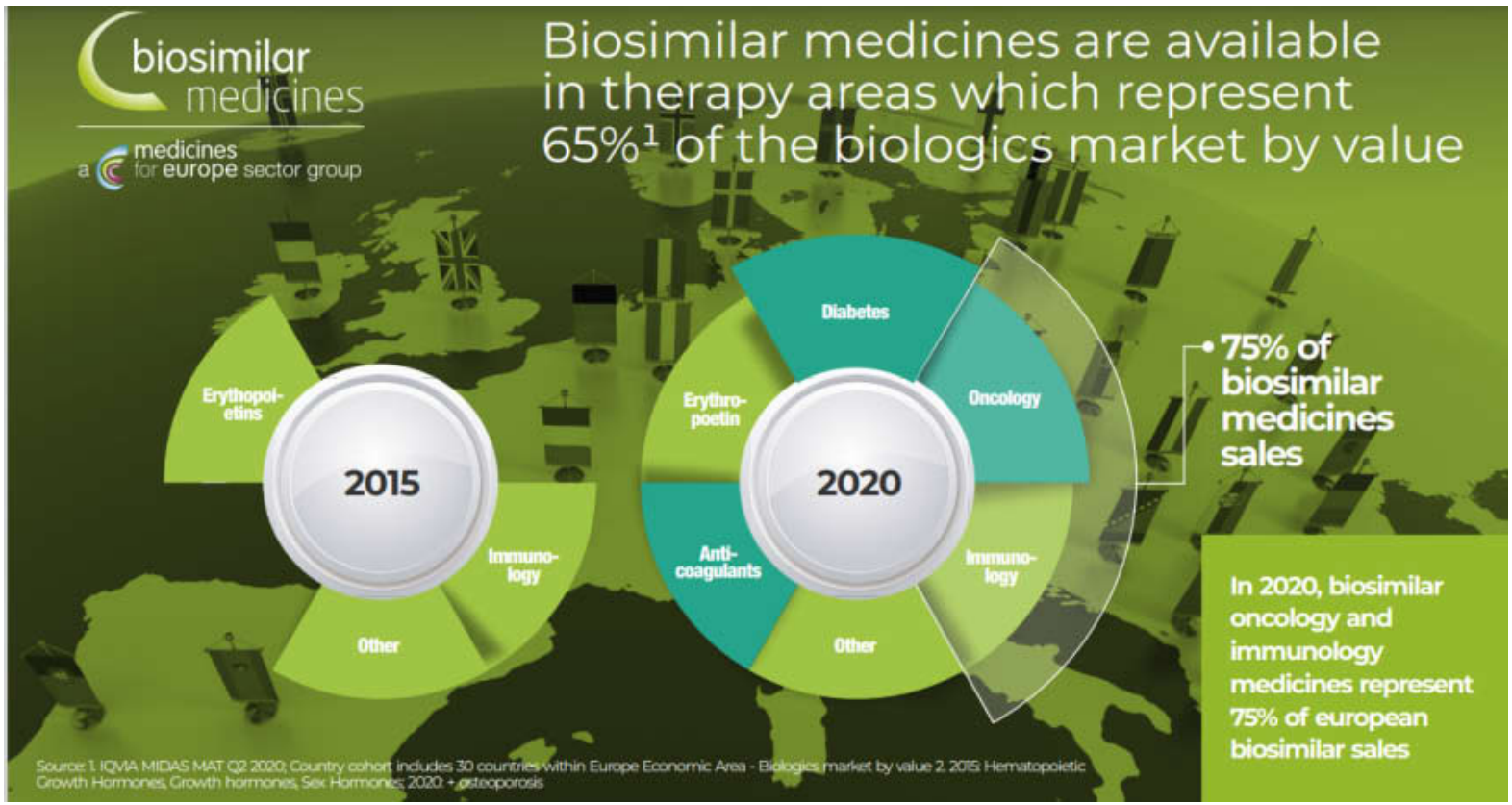
Directive 2001/83/EC, Annex I, Part I, 3.2.1.1.

CATEGORIES OF BIOLOGICAL MEDICINES

- Immunological medicinal products
- Medicinal products derived from human blood and human plasma
- Advanced therapy medicinal products
- Medicinal products developed by means of one of the following biotechnological processes:
  - recombinant DNA technology,
  - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells,
  - hybridoma and monoclonal antibody methods.

Directive 2001/83/EC, Annex I, Part I, 3.2.1.1.

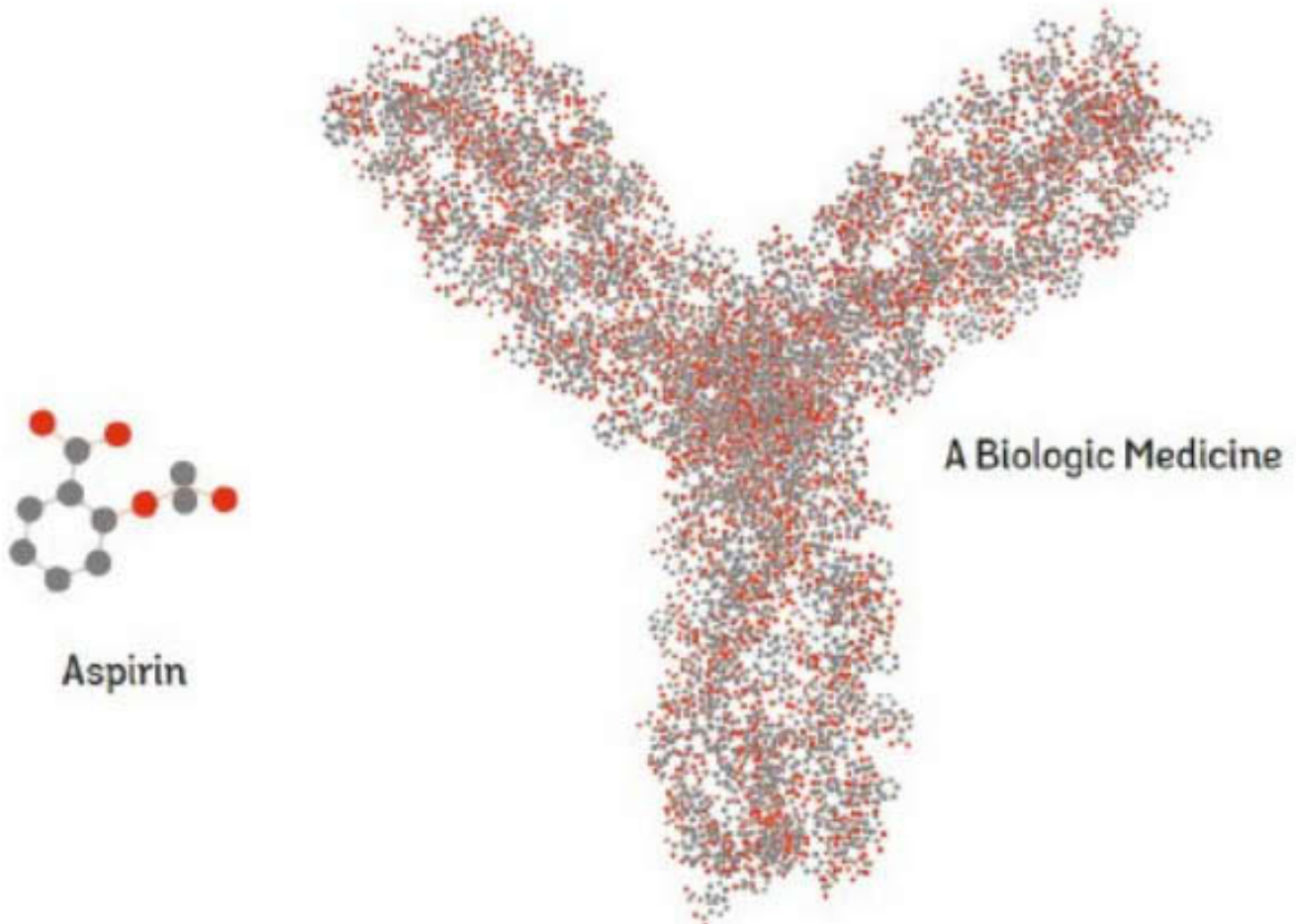
THERAPEUTIC FIELDS



BIOSIMILAR VS GENERIC

Key technical & Scientific differences

BIOSIMILAR	GENERIC
Biological product	Chemical product
Large, complex molecules	Relatively small, simple molecules
Produced by modifying and reproducing biological material obtained from living organisms	Typically produced by chemical synthesis
Greater immunogenicity potential	Lower immunogenicity potential
SIMILAR, but never identical, to reference medicine	Potentially IDENTICAL to reference medicine



Source: www.crohnsandcolitis.org.uk

BIOSIMILAR VS GENERIC

Key economic & regulatory differences

BIOSIMILAR	GENERIC
5 - 8 years development	2 - 3 years development
10 - 300 M € development	1 - 3 M € development
Generally can only be authorised through EMA centralised procedure	Can be generally authorised by Member States through different procedures
Require comprehensive comparability (biosimilarity) studies, including clinical studies, prior to authorization. Additional monitoring (❑) post authorisation	Just bioequivalence (mainly PK) studies prior to authorization. No special monitoring post authorisation
Prescribed by brand name	Can be prescribed by active ingredient (INN)
Relatively new phenomenon (first biosimilar – somatropin- authorised in EU in 2006)	Used (and litigated) for decades

Impact on patent litigation strategies?

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TOPICS FOR DISCUSSION

LAUNCH: PIs & CLEARING THE PATH

PIs available?

Irreparable harm required? Do local (non-) interchangeability / (non-) replaceability / (non-) switching rules or practices impact on establishing irreparable harm?

Balance of interests considered?

Clearing-the-path strategies?

REMEDIES: INJUNCTION AND DAMAGES

Are injunctions an "automatic remedy"?
Even against bio-betters?

Do local (non-) interchangeability / (non-)replaceability / (non-) switching rules or practices impact on establishing damages?

EVIDENCE GATHERING

Proof of infringement

PANEL MEMBERS

MODERATOR

Álvaro de Castro

ES

GA_P Gómez-Acebo & Pombo | 50 Aniversario

Gabriella Bornstein

UK

KIRKLAND & ELLIS

Mark Egeler

NL

Freshfields

Tobias Weigand

DE

ARNOLD & RUESS

TOPICS FOR DISCUSSION

LAUNCH: PIs & CLEARING THE PATH

Are you likely to be able to get a Preliminary Injunction to prevent launch of a biosimilar?

TOPICS FOR DISCUSSION

LAUNCH: PIs & CLEARING THE PATH

Can you deploy a public interest defence to avoid an injunction (preliminary or final)?

TOPICS FOR DISCUSSION

LAUNCH: PIs & CLEARING THE PATH

What options do biosimilar manufacturers have to clear the path to avoid PI threats?

TOPICS FOR DISCUSSION

REMEDIES: INJUNCTION AND DAMAGES

Are there any special considerations for Biosimilars with regard to injunctions?

TOPICS FOR DISCUSSION

REMEDIES: INJUNCTION AND DAMAGES

Are there any special considerations for Biosimilars with regard to damage calculation?

TOPICS FOR DISCUSSION

EVIDENCE GATHERING

Are there any legal tools or options to facilitate proof of infringement in biosimilar cases?

I WANT YOU TO VOTE

Thank you.