Biosimilar Litigation Strategies

YOUNG EPLAW CONGRESS

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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

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.

THERAPEUTIC FIELDS

Biosimilar medicines are available in therapy areas which represent 65%¹ of the biologics market by value.

In 2020, biosimilar oncology and immunology medicines represent 75% of European biosimilar sales.

**BIOSIMILAR VS GENERIC**

<table>
<thead>
<tr>
<th>BIOSIMILAR</th>
<th>GENERIC</th>
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<tbody>
<tr>
<td>Biological product</td>
<td>Chemical product</td>
</tr>
<tr>
<td>Large, complex molecules</td>
<td>Relatively small, simple molecules</td>
</tr>
<tr>
<td>Produced by modifying and reproducing biological material obtained from</td>
<td>Typically produced by chemical synthesis</td>
</tr>
<tr>
<td>living organisms</td>
<td></td>
</tr>
<tr>
<td>Greater immunogenicity potential</td>
<td>Lower immunogenicity potential</td>
</tr>
<tr>
<td>SIMILAR, but never identical, to reference medicine</td>
<td>Potentially IDENTICAL to reference medicine</td>
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# BIOSIMILAR VS GENERIC

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<th>BIOSIMILAR</th>
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<tr>
<td>5 - 8 years development</td>
<td>2 - 3 years development</td>
</tr>
<tr>
<td>10 - 300 M € development</td>
<td>1 - 3 M € development</td>
</tr>
<tr>
<td>Generally can only be authorised through EMA centralised procedure</td>
<td>Can be generally authorised by Member States through different procedures</td>
</tr>
<tr>
<td>Require comprehensive comparability (biosimilarity) studies, including clinical studies, prior to authorization. Additional monitoring (_popup) post authorisation</td>
<td>Just bioequivalence (mainly PK) studies prior to authorization. No special monitoring post authorisation</td>
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<tr>
<td>Prescribed by brand name</td>
<td>Can be prescribed by active ingredient (INN)</td>
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<tr>
<td>Relatively new phenomenon (first biosimilar – somatropin- authorised in EU in 2006)</td>
<td>Used (and litigated) for decades</td>
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Impact on patent litigation strategies?
I WANT YOU TO VOTE
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
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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?
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Thank you.