The valorization of probiotic products: insight into intellectual property and clinical research
Microbiota-targeting interventions to improve health

Autoimmune, metabolic, and (newly emerging) infectious diseases

Probiotics as potential clinical modalities

Many promising studies, but what is happening globally?

Studying the status of valorization of probiotics as clinical modalities

- Patents for the long term and clinical trials for the short term\textsuperscript{4,5}
- Intellectual property since 1999

1. Total landscape
2. Infectious diseases
3. Gut-brain related indications
4. Searches in patent and clinical trial databases

\begin{tabular}{|l|l|}
\hline
CPC/IPC code & Description Espacenet \\
\hline
A61K2035/115 & “Probiotics” \\
A61K35/741 & “Probiotics (probiotic yeast, e.g., saccharomyces)” \\
A61K35/742 & “Spore-forming bacteria, e.g., Bacillus coagulans, Bacillus subtilis, clostridium or Lactobacillus sporogenes” \\
A61K35/744 & “Lactic acid bacteria, e.g., enterococci, pediococci, lactococci, streptococci or leuconostocs” \\
A61K35/745 & “Bifidobacteria” \\
A61K35/747 & “Lactobacilli, e.g., L. acidophilus or L. brevis” \\
A23L33/135 & “Bacteria or derivatives thereof, e.g., probiotics” \\
\hline
\end{tabular}

Investigation of patent and clinical trial records

Analysis based on:
- Studied indication
- Probiotic product type
- Location
- Sponsor/funder type
- Year of application

Total results
N = 18,298

Included records
N = 4,863

67 infectious diseases
83 gut-brain indications
Global landscape of clinical trials as short-term valorization

Cumulative number of clinical trials

Year


Africa  Asia  Europe  North America  Oceania  South America
Global landscape of clinical trials as short-term valorization

Product types in Europe (n = 900)
Focusing on specific indications:
clinical trials and patents for infectious diseases

<table>
<thead>
<tr>
<th>Patents</th>
<th>Clinical trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 <em>Escherichia coli</em> infection</td>
<td><em>Helicobacter pylori</em> infection</td>
</tr>
<tr>
<td>2 <em>Helicobacter pylori</em> infection</td>
<td>Antibiotic-associated diarrhea</td>
</tr>
<tr>
<td>3 Bacterial vaginosis</td>
<td>Bacterial vaginosis</td>
</tr>
<tr>
<td>4 <em>Clostridium difficile</em> infection</td>
<td>Gastroenteritis</td>
</tr>
<tr>
<td>5 Candidiasis</td>
<td>Pneumonia</td>
</tr>
</tbody>
</table>

![Graph showing cumulative number of patents and clinical trials over years]
Focusing on specific indications: clinical trials and patents for gut-brain indications

<table>
<thead>
<tr>
<th>Patents</th>
<th>Clinical trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Irritable bowel syndrome</td>
</tr>
<tr>
<td>2</td>
<td>Depression (general)</td>
</tr>
<tr>
<td>3</td>
<td>Alzheimer’s disease</td>
</tr>
<tr>
<td>4</td>
<td>Stress (general)</td>
</tr>
<tr>
<td>5</td>
<td>Anxiety (general)</td>
</tr>
<tr>
<td></td>
<td>Autism spectrum disorder</td>
</tr>
<tr>
<td></td>
<td>Parkinson’s disease</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain</td>
</tr>
</tbody>
</table>
From IP to physical product

Infectious diseases

Gut-brain indications
Possible factors related to valorization

- Different types of indications
  - Practicalities of outcome measures
  - Gastrointestinal infections, stress
- Recent stagnation of growth
  - High costs vs expected profits
  - Saturation of intellectual property space
- Other factors
  - Regulations
  - Current events
- Application in practice
  - Follow-up studies
  - Elderly care and dietetics

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Conclusions

• Growing body of intellectual property → growing interest

• Delay between patents and clinical trials → possible barriers

• Facilitation of transition from industry to practical application of probiotics is needed
Thank you

• Eveline van Beek, MSc
• Linda van de Burgwal, PhD
• Mariët Veerman, MSc
• Olaf Larsen, PhD
• Robert Jan Brummer, MD, PhD