Emerging Leaders in Generics
Successful Strategies for Growth
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Objectives

- Identify successful growth strategies by benchmarking against current leaders
- Reveal the competitive landscape
- Explore potential growth accelerators
A highly fragmented manufacturing landscape
3,200+ companies involved in API production

- Established: Companies with years of experience supplying active ingredients to regulated market.
- Less Established: Less of a track record in supplying to regulated markets, either in terms of years of history or number of products supplied. Still considered as capable of supplying regulated markets.
- Potential Future: Interest in supplying regulated markets, but with limited or no known performance.
- Local: Supplying only to their local and other less-regulated markets; do not currently have the capability of passing inspections by regulatory bodies like the US FDA.
- Big Pharma: Innovative companies with at least $1.0B USD in annual R&D expenditures.
- Unrated: Companies for which Newport has not assigned a rating.

Source: The Changing Dynamics of Global API Manufacturing, Clarivate Analytics
Our focus today
Manufacturers commercially active in international markets

Potential Future: 582
Less Established: 130
Established: 215
Total Sample: 927
Growth Model

- Horizontal expansion: more products and new markets/territories
- Vertical expansion: more complex, higher margin activities
Can the past still be our guide?
Recent changes to the market environment

Past conditions
• High volume primary care
• Fewer incumbents
• Sole exclusivity
• Lower barriers to entry
• Transactional relationships (in contract services)

Conditions today
• Low volume specialty
• Aggressive new entrants
• Shared exclusivity
• Facility & GDUFA fees
• Strategic/shared accountability (in contract services)
Horizontal Expansion
More Products

Horizontal expansion

- Benchmarking portfolio sizes across maturity levels
- Regional strategies

- India and Mainland China focused on achieving scale and breadth
- US-, Japan-, EU-based manufacturers more likely to be niche specialists

Source: Newport, a Cortellis solution
Portfolio Breadth

- Outliers influence the math and the market
- Gap between India and China is closing
- Top 50% of Established firms bigger than almost all other companies
- 20-API threshold for strategic choices

Portfolio Breadth

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<th>Medians</th>
<th>Total</th>
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Source: Newport, a Cortellis solution
Growth benchmarks in portfolio strategy
Distribution of Confirmed APIs vs. Active manufacturing filings

- Global / international scale along with larger product portfolios
- Thresholds around 20 and 100 APIs

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- Global / international scale along with larger product portfolios
- Thresholds around 20 and 100 APIs
- Not fully globalized yet
- Active mostly in less regulated markets
- Signs of entry into regulated markets
- Potential for additional competitive pressure

Source: Newport, a Cortellis solution
Visualizing the strategic landscape
Distribution of Confirmed APIs vs. Active manufacturing filings

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Source: Newport, a Cortellis solution
Vertical Expansion
Diversification of capabilities

Vertical expansion

- Two-thirds of Established firms affiliated with finished dose or US Generics activity
  - 56% of Less Established
  - 33% of Potential Future

API Only
Companies only associated with API manufacturing.

Dose
Companies with a finished dose subsidiary, which can include OTC marketers, generics without U.S. presence and parallel importers

US Generic
Companies that have a generic finished dose presence in the United States.

Biotech
Companies associated with biologic products.

Small Innovator
Corporations with in-house R&D, but with a small number of innovative products and a regional sales and marketing focus.

US Specialty
Generic companies that have several branded products in the United States which are unique formulations.

Source: Newport, a Cortellis solution
Capabilities expand with maturity
Distribution of Confirmed APIs vs. Active manufacturing filings

- Specialists and start-ups
- Trade-off of more APIs vs. new capabilities

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Capabilities expand with maturity
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- Specialists and start-ups
- Trade-off of more APIs vs. new capabilities
- Not fully globalized yet
- Potential new competitors in US and/or European markets

Source: Newport, a Cortellis solution
Capabilities expand with maturity
Distribution of Confirmed APIs vs. Active manufacturing filings

- Specialists and start-ups
- Trade-off of more APIs vs. new capabilities

- Not fully globalized yet
- Potential new competitors in US market

- Achievement of scale pushes firms to diversify toward higher margin activities

Source: Newport, a Cortellis solution
• FDA remains active
• Gap between foreign and domestic visits closing
• Indications of potential new entrants to USA

• 58 Potential Future suppliers have been inspected since 2016 but do not hold active DMFs... yet
  – 13 have a regulatory track record in Europe (i.e., active COS)

Source: Newport, a Cortellis solution
The BIG question

• What will be the effect of stricter regulatory schemes in China and India?
Growth Accelerators
New API types
Growth Accelerators

- High potency active ingredients
- Controlled substances
- Antibiotics
- Peptides, proteins, recombinant formulations
- Mono-, polyclonal antibodies

- Dedicated facilities
- Enhanced containment technologies
- Specialized equipment (e.g., lyophilization, micronization)
The Newport Constraint Date (NCD) is a proprietary algorithm that considers patents, market exclusivities and data exclusivities for a specific product in a specific country/territory and estimates the earliest date that a generic could enter the market when the product loses patent or exclusivity protection.

- 300+ unique products potentially face first-time generic competition in just three large markets
- 60 facing loss of exclusivity in more than one of these markets

US count of products excludes those under active Paragraph Four litigation

Source: Newport, a Cortellis solution
Increasing complexity of new opportunities

Route of Administration of in-sample products with upcoming NCDs

- **Oral Solids**: 166
- **Parenterals (Small molecule)**: 65
- **Ophthalmic**: 8
- **Inhalation**: 11
- **Topicals**: 14
- **Parenterals (Protein / Biologic)**: 87

Source: Newport, a Cortellis solution
US leads the first worldwide launches followed by Japan and China

- 39 first-in-world launches in the US
- 9 launches in Japan, followed by 4 in China
- Cambodia had its first first-in-world launch

Source: 2019 CMR Pharmaceutical R&D Factbook
2018 US FDA Novel Drug Approvals
Continuing shift to specialty therapeutics

- **59** New Molecular Entities
- **42** Small Molecules
- **17** Biologics
- **22** Orphan Drugs
- **20** Oncology-focused

Source: US FDA
2018 US FDA Novel Drug Approvals
Continuing shift to specialty therapeutics

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</tbody>
</table>

Capturing value from new products requires diverse, specialized capabilities

Source: US FDA
Outlook

• Characteristics of an emerging leader

• Inflection point benchmarks

• International to global in scope
• Near or above 20-product benchmark
• Diversifying capabilities
• Increasingly investing in more complex, higher margin activities
• Pursuing first-time generic opportunities
• Able to maintain quality standards
Characteristics of an emerging leader

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Leadership is not unidimensional
Questions?
Going to CPhI Worldwide?

Meet us at Booth 42F33
Frankfurt, Germany
November 5-7, 2019
Thank you

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