

STAFF REPORT

Active Pharmaceutical Ingredients:

Global Markets to 2022

July 2018

BCC Research Staff

Report Code: PHM200A

Table of Contents

Chapter 1: Introduction	1
Study Goals and Objectives.....	1
Reasons for Doing This Study.....	1
Scope of Report.....	1
Information Sources.....	1
Methodology.....	2
Geographic Breakdown.....	2
Analyst's Credentials.....	7
Related BCC Research Reports.....	7
Chapter 2: Summary and Highlights	9
Highlights	10
Chapter 3: Active Pharmaceutical Ingredients - Introduction	12
Pharmaceutical Industry Overview.....	12
Patent Expiry and Its Impact on the Pharmaceutical Market	13
Changes in Pharmaceutical Drug Development.....	13
Drug Discovery and Development Process	13
Target Identification and Validation.....	13
Technologies for Drug Discovery.....	14
API-Definition.....	15
Sources of APIs	15
API Production Methods.....	16
API Production-Route of Synthesis.....	16
Production Methods	19
Regulatory Perspective on Production Methods	20
Active Pharmaceutical Ingredient Market	20
Market Dynamics	21
Market Drivers.....	22
Market Challenges.....	26
Emerging Trends.....	29
Current State of Active Pharmaceutical Ingredient Regulations	31
Harmonization of API GMP Standards and Supply Chain Integrity.....	33
Chapter 4: Active Pharmaceutical Ingredients Market by Manufacturer/ Service Provider	35
Introduction and Global Markets.....	35
The API Market by Manufacturer Type.....	35
Captive Market: Market Analysis.....	38
Overview	38
Market Size and Forecast	38
Merchant Market: Market Analysis	42
Overview	42
Market Size and Forecast	43
Contract Manufacturing Organizations (CMOs): Market Analysis.....	46
Overview	46
Market Size and Forecast	48
Chapter 5: API Market by End Use	54
Introduction and Global Markets.....	54
Clinical Trial: Market Analysis	57

Overview	57
Market Size and Forecast	58
Commercial: Market Analysis	68
Overview	68
Market Size and Forecast	69
Chapter 6 API by Origin	74
Introduction and Market Analysis.....	74
Natural Origin: Types and Market Analysis.....	77
Plants Sources	77
Animal Sources	78
Others.....	78
Market Size and Forecast.....	79
Synthetic APIs: Types and Market Analysis	82
Overview	82
Market Size and Forecast	82
Chemical Synthesis: Introduction and Market Analysis	88
Biocatalysis: Introduction and Market Analysis	89
Cell Culture Methods: Introduction and Market Analysis.....	90
Chapter 7: API Market by Molecule Type	93
Introduction and Global Markets.....	93
Small Molecules: Types and Market Analysis	96
Market Size and Forecast	99
Branded Small Molecule APIs.....	103
Generic APIs	106
Biologics: Types and Market Analysis	108
Market Size and Forecast	110
Branded Biologic APIs.....	117
Biosimilar APIs	119
Chapter 8: API Market by Region	123
Introduction and Regional Market.....	123
North America.....	127
Overview	127
Market Size by Country	128
Europe.....	130
Overview	130
Market Size by Country	131
Asia-Pacific	133
Overview	133
Market Size by Country	134
Rest of the World	136
Overview	136
Chapter 9: Supplier Landscape and Key Industry Development	141
Supplier Landscape	141
Reasons for Fragmentation	142
List of Other Key API Manufacturers by Region	143
Porter's Five Force Analysis	146
Threat of New Entrants	146
Threat of Substitute Products or Services.....	148
Bargaining Power of Customers (Buyers).....	148

Bargaining Power of Suppliers	149
Intensity of Competitive Rivalry	150
Chapter 10: Company Profiles	153
Appendix.....	221
Abbreviations	221
About BCC Research.....	223
About BCC Research.....	224
BCC Membership	224
BCC Custom Research	224

List of Tables

Summary Table: Global Market for API, by Manufacturer, Through 2022 (\$ Millions)	9
Table 1 Advantages and Disadvantages of Using Natural APIs	15
Table 2 Advantages and Disadvantages of Using Synthetic APIs	16
Table 3 Top Selling Brands and Their Patent Expiry, 2012-2017	23
Table 4 API Manufacturers: Manufacturing Facility Expansion	30
Table 5 Regulatory Requirements of GMP and Supply Chain Integrity for APIs	32
Table 6 Global Market for API, by Manufacturer, Through 2022 (\$ Millions)	35
Table 7 Global Market for Captive API, by Region, Through 2022 (\$ Millions)	40
Table 8 Global Market for Merchant API, by Region Through 2022 (\$ Millions)	44
Table 9 Global Market for CMO API, by Region, Through 2022 (\$ Millions)	49
Table 10 Global Market for API, by End Use, Through 2022 (\$ Millions)	55
Table 11 Global Market for Clinical Trial API, by Region, Through 2022 (\$ Millions)	66
Table 12 Global Market for Commercial API, by Region, Through 2022 (\$ Millions)	70
Table 13 Global Market for API, by Origin, Through 2022 (\$ Millions)	74
Table 14 Global Market for Natural API, by Region, Through 2022 (\$ Millions)	80
Table 15 Global Market for Synthetic API, by Region, Through 2022 (\$ Millions)	84
Table 16 Global Market for Synthetic API, by Type, Through 2022 (\$ Millions)	86
Table 17 Advantages and Disadvantages of the Biocatalytic Process	89
Table 18 Cell Culture Types: Attributes and Applications	90
Table 19 Global Market for APIs, by Molecule Type, Through 2022 (\$ Millions)	93
Table 20 Characteristics of Small Molecules, by Parameters	97
Table 21 Top Selling Small Molecule Drugs, 2015	98
Table 22 Global Market for Small Molecule APIs, by Type, Through 2022 (\$ Millions)	101
Table 23 Global Market for Branded Small Molecule APIs, by Region, Through 2022 (\$ Millions)	104
Table 24 Global Market for Generic Small Molecule APIs, by Region, Through 2022 (\$ Millions)	107
Table 25 Characteristics of Large Molecules/Biologics, by Parameters	109
Table 26 Top Selling Biologics, 2015 (\$ Billions)	109
Table 27 Global Market for Large Molecule APIs, by Region, Through 2022 (\$ Millions)	112
Table 28 Global Market for Large Molecule APIs, by Type, Through 2022 (\$ Millions)	114
Table 29 Global Market for Branded APIs, by Region, Through 2022 (\$ Millions)	118
Table 30 Global Market for Biosimilar APIs, by Region, Through 2022 (\$ Millions)	120
Table 31 Global Market for API, by Region, Through 2022 (\$ Millions)	123
Table 32 North America Market for APIs, by Country, Through 2022 (\$ Millions)	128
Table 33 Europe Market for APIs, by Country, Through 2022 (\$ Millions)	131
Table 34 Asia-Pacific Market for APIs, by Country, Through 2022 (\$ Millions)	134
Table 35 RoW Market for APIs, by Country, Through 2022 (\$ Millions)	137
Table 36 Other API Manufacturers, North America	143
Table 37 Other API Manufacturers, Europe	143
Table 38 Other API Manufacturers, Asia-Pacific	144
Table 39 Key Industry Developments in API Market, March 2015-October 2017	144
Table 40 Teva Pharmaceutical Financials, 2015-2017 (\$ Millions)	154
Table 41 Teva Pharmaceutical API Manufacturing Facilities	159
Table 42 Teva Pharmaceutical Products and Services	160
Table 43 Cambrex Financials, 2015-2017 (\$ Millions)	162
Table 44 Cambrex API Manufacturing Facilities	164
Table 45 Cambrex Products and Services	165
Table 46 Siegfried Financials, 2015-2017 (\$ Millions)	167

Table 47 Siegfried Products and Services	169
Table 48 Cordon Pharma Manufacturing Facilities.....	170
Table 49 Cordon Pharma Products and Services	171
Table 50 Aurobindo Pharma Financials, 2015-2017 (\$ Millions)	173
Table 51 Aurobindo Pharma Products and Services.....	178
Table 52 BASF Financials, 2015-2017 (\$ Billions).....	180
Table 53 BASF Products and Services	184
Table 54 Dishman Group Financials, 2015-2017 (\$ Millions)	185
Table 55 Dishman Group Manufacturing Facilities.....	188
Table 56 Dishman Group Products and Services	189
Table 57 Mylan Financials, 2014-2016 (\$ Millions).....	190
Table 58 Mylan Products and Services	193
Table 59 AMRI Financials, 2014-2016 (\$ Millions).....	194
Table 60 AMRI Manufacturing Facilities	198
Table 61 AMRI Products and Services.....	199
Table 62 Avid Bioservices Financials, 2015-2017 (\$ Millions).....	201
Table 63 Halo Pharma Capabilities	202
Table 64 Lonza Financials, 2015-2017 (\$ Millions)	203
Table 65 Lonza Products and Services	208
Table 66 Sun Pharmaceutical Financials, 2015-2017 (\$ Millions).....	210
Table 67 Sun Pharmaceutical Products and Services	212
Table 68 Dr Reddy's Laboratory Manufacturing Facilities	213
Table 69 Dr Reddy's Laboratory Financials, 2015-2017 (\$ Millions).....	213

List of Figures

Summary Figure: Global Market for API, by Manufacturer, 2016-2022 (\$ Millions)	10
Figure 1 Global Market Share for the Pharmaceutical Industry, by Region, 2016 (%)	12
Figure 2 API Production, by Chemical Synthesis	17
Figure 3 API Production, by Biological Process	18
Figure 4 API Production, by Natural Sources-Extraction Process	19
Figure 5 Global Market for APIs, 2016-2022 (\$ Millions).....	20
Figure 6 Active Pharmaceutical Ingredients: Market Dynamics	22
Figure 7 Number of ANDA Filings, Drug Approvals and Approval Success Rate, 2013-2017	24
Figure 8 Number of BLA Approvals, 2008-2015.....	25
Figure 9 Trends in U.S. FDA Foreign Inspection, 2011-2016.....	26
Figure 10 Number of FDA Inspections in Foreign Countries, by Country, 2011-2016.....	27
Figure 11 Trends in FDA Warning Calls, 2015-2016.....	28
Figure 12 Global Market for API, by Manufacturer, 2016-2022 (\$ Millions).....	36
Figure 13 Global Market Share for API, by Manufacturer, 2016 (%)	37
Figure 14 Global Market Share for API, by Manufacturer, 2022 (%)	38
Figure 15 Global Market for Captive API, 2016-2022 (\$ Millions)	39
Figure 16 Global Market for Captive API, by Region, 2016-2022 (\$ Millions)	40
Figure 17 Global Market Share for Captive API, by Region, 2016 (%)	41
Figure 18 Global Market Share for Captive API, by Region, 2022 (%)	42
Figure 19 Global Market for Merchant API, 2016-2022 (\$ Millions)	43
Figure 20 Global Market for Merchant API, by Region, 2016-2022 (\$ Millions)	44
Figure 21 Global Market Share for Merchant API, by Region, 2016 (%).....	45
Figure 22 Global Market Share for Merchant API, by Region, 2022 (%).....	46
Figure 23 Global Market for CMO API, 2016-2022 (\$ Millions)	48
Figure 24 Global Market for CMO API, by Region, 2016-2022 (\$ Millions)	50
Figure 25 Global Market Share for CMO API, by Region, 2016 (%)	51
Figure 26 Global Market Share for CMO API, by Region, 2022 (%)	52
Figure 27 API Production Flow: From Clinical Development to Large Scale Manufacture.....	54
Figure 28 Global Market for API, by End Use, 2016-2022 (\$ Millions)	55
Figure 29 Global Market Share for API, by End Use, 2016 (%)	56
Figure 30 Global Market Share for API, by End Use, 2022 (%)	57
Figure 31 Global Market for Clinical Trial API, 2016-2022 (\$ Millions).....	58
Figure 32 Number of New Molecular Entities (NMEs) in Different Phases of Drug Development, 2012-2016	59
Figure 33 Biologics Research and Development.....	60
Figure 34 Biologics Development, by Therapeutic Area	61
Figure 35 Funding Scenario, 2012-2017 (\$ Billions).....	62
Figure 36 Orphan Drug Clinical Development, 2012-2016	63
Figure 37 Clinical Trials, by Region, 2015.....	64
Figure 38 Mortality Rates of Selected Diseases, by Country, 2020	65
Figure 39 Global Market for Clinical Trial API, by Region, 2016-2022 (\$ Millions).....	66
Figure 40 Global Market Share for Clinical Trial API, by Region, 2016 (%)	67
Figure 41 Global Market Share for Clinical Trial API, by Region, 2022 (%)	68
Figure 42 Global Market for Commercial API, 2016-2022 (\$ Millions).....	69
Figure 43 Global Market for Commercial API, by Region, 2016-2022 (\$ Millions).....	70
Figure 44 Global Market Share for Commercial API, by Region, 2016 (%)	71
Figure 45 Global Market Share for Commercial API, by Region, 2022 (%)	72

Figure 46 Global Market for API, by Origin, 2016-2022 (\$ Millions).....	75
Figure 47 Global Market Share for API, by Origin, 2016 (%).....	76
Figure 48 Global Market Share for API, by Origin, 2022 (%).....	77
Figure 49 Global Market for Natural API, by Region, 2016-2022 (\$ Millions)	79
Figure 50 Global Market for Natural API, by Region, 2016-2022 (\$ Millions)	80
Figure 51 Global Market Share for Natural API, by Region, 2016 (%)	81
Figure 52 Global Market Share for Natural API, by Region, 2022 (%)	82
Figure 53 Global Market for Synthetic API, 2016-2022 (\$ Millions)	83
Figure 54 Global Market for Synthetic API, by Region, 2016-2022 (\$ Millions)	84
Figure 55 Global Market Share for Synthetic API, by Region, 2016 (%)	85
Figure 56 Global Market Share for Synthetic API, by Region, 2022 (%)	86
Figure 57 Global Market for Synthetic API, by Type, 2016-2022 (\$ Millions).....	87
Figure 58 Global Market for Chemical Synthetic API, 2016-2022 (\$ Millions).....	88
Figure 59 Global Market for Biocatalytic APIs, 2016-2022 (\$ Millions)	90
Figure 60 Global Market for Cell Culture APIs, 2016-2022 (\$ Millions).....	91
Figure 61 Global Market for APIs, by Molecule Type, 2016-2022 (\$ Millions).....	94
Figure 62 Global Market Share for APIs, by Molecule Type, 2016 (%)	95
Figure 63 Global Market Share for APIs, by Molecule Type, 2022 (%)	96
Figure 64 Number of Small Molecules in Clinical Pipeline (\$ Millions).....	97
Figure 65 Number of Small Molecules Approved, 2010-2016 (\$ Millions).....	99
Figure 66 Global Market for Small Molecule APIs, 2016-2022 (\$ Millions)	100
Figure 67 Global Market for Small Molecule APIs, by Type, 2016-2022 (\$ Millions)	101
Figure 68 Global Market Share for Small Molecule APIs, by Type, 2016 (%)	102
Figure 69 Global Market Share for Small Molecule APIs, by Type, 2022 (%)	103
Figure 70 Global Market for Branded Small Molecule APIs, 2016-2022 (\$ Millions)	104
Figure 71 Global Market for Branded Small Molecule APIs, by Region, 2016-2022 (\$ Millions).....	105
Figure 72 Global Market for Generic Small Molecule APIs, 2016-2022 (\$ Millions)	106
Figure 73 Global Market for Generic Small Molecule APIs, by Region, 2016-2022 (\$ Millions).....	107
Figure 74 New Biological Entities Approved, 2010-2016 (\$ Millions).....	110
Figure 75 Global Market for Biologics/Large Molecules APIs, 2016-2022 (\$ Millions)	111
Figure 76 Global Market for Large Molecule APIs, by Region, 2016-2022 (\$ Millions)	112
Figure 77 Global Market Share for Large Molecule APIs, by Region, 2016 (%)	113
Figure 78 Global Market Share for Large Molecule APIs, by Region, 2022 (%)	114
Figure 79 Global Market for Large Molecule APIs, by Type, 2016-2022 (\$ Millions)	115
Figure 80 Global Market Share for Large Molecule APIs, by Type, 2016 (%)	116
Figure 81 Global Market Share for Large Molecule APIs, by Type, 2022 (%)	117
Figure 82 Global Market for Branded APIs, 2016-2022 (\$ Millions).....	118
Figure 83 Global Market for Branded APIs, by Region, 2016-2022 (\$ Millions)	119
Figure 84 Global Market for Biosimilar APIs, 2016-2022 (\$ Millions).....	120
Figure 85 Global Market for Biosimilar APIs, by Region, 2016-2022 (\$ Millions).....	121
Figure 86 Global Market for APIs, by Region, 2016-2022 (\$ Millions).....	124
Figure 87 Global Market Share for APIs, by Region, 2016 (%).....	125
Figure 88 Global Market Share for APIs, by Region, 2022 (%).....	126
Figure 89 North America Market for APIs, by Country, 2016-2022 (\$ Millions).....	128
Figure 90 North America Market Share for APIs, by Country, 2016 (%).....	129
Figure 91 North America Market Share for APIs, by Country, 2022 (%).....	130
Figure 92 Europe Market for APIs, by Country, 2016-2022 (\$ Millions).....	131
Figure 93 Europe Market Share for APIs, by Country, 2016 (%)	132
Figure 94 Europe Market Share for APIs, by Country, 2022 (%).....	133
Figure 95 Asia-Pacific Market for APIs, by Country, 2016-2022 (\$ Millions)	134
Figure 96 Asia-Pacific Market Share for APIs, by Country, 2016 (%)	135

Figure 97 Asia-Pacific Market Share for APIs, by Country, 2022 (%)	136
Figure 98 RoW Market for APIs, by Country, 2016-2022 (\$ Millions).....	137
Figure 99 RoW Market Share for APIs, by Country, 2016 (%).....	138
Figure 100 RoW Market Share for APIs, by Country, 2022 (%).....	139
Figure 101 Global Market Share of Selected API Manufacturers, 2016 (%).....	141
Figure 102 Porter's Five Force Analysis-Overview	146
Figure 103 Threat of New Entrants.....	147
Figure 104 Threat of Substitute Products or Services	148
Figure 105 Bargaining Power of Customers (Buyers)	149
Figure 106 Bargaining Power of Suppliers	150
Figure 107 Intensity of Competitive Rivalry.....	151
Figure 108 Teva Pharmaceutical Revenue, by Business Segment, 2015-2017 (\$ Millions).....	155
Figure 109 Teva Pharmaceutical Revenue Share, by Business Segment, 2017 (%).....	156
Figure 110 Teva Pharmaceutical Revenue, by Region, 2015-2017 (\$ Millions).....	157
Figure 111 Teva Pharmaceutical Revenue Share, by Region, 2017 (%).....	158
Figure 112 Cambrex Revenue, by Region, 2015-2017 (\$ Millions).....	163
Figure 113 Cambrex Revenue Share, by Region, 2017 (%)	164
Figure 114 Siegfried Revenue, by Product, 2015-2017 (\$ Millions)	167
Figure 115 Siegfried Revenue Share, by Product, 2017 (%).....	168
Figure 116 Aurobindo Pharma Revenue, by Business Segment, 2015-2017 (\$ Millions).....	174
Figure 117 Aurobindo Pharma Revenue Share, by Business Segment, 2017 (%).....	175
Figure 118 Aurobindo Pharma Revenue, by Region, 2015-2017 (\$ Millions).....	176
Figure 119 Aurobindo Pharma Revenue Share, by Region, 2017 (%).....	177
Figure 120 BASF Revenue, by Business Segment, 2015-2017 (\$ Billions)	180
Figure 121 BASF Revenue Share, by Business Segment, 2017 (%)	181
Figure 122 BASF Market, by Region, 2015-2017 (\$ Millions)	182
Figure 123 BASF Revenue Share, by Region, 2017 (%)	183
Figure 124 Dishman Group Revenue, by Product, 2015-2017 (\$ Millions)	186
Figure 125 Dishman Group Revenue Share, by Product, 2017 (%)	187
Figure 126 Mylan Revenue, by Region, 2014-2016 (\$ Millions)	191
Figure 127 Mylan Revenue Share, by Region, 2016 (%)	192
Figure 128 AMRI Revenue, by Business Segment, 2014-2016 (\$ Millions)	195
Figure 129 AMRI Revenue Share, by Business Segment, 2016 (%).....	196
Figure 130 AMRI Revenue, by Region, 2014-2016 (\$ Millions).....	197
Figure 131 Lonza Revenue, by Business Segment, 2015-2017 (\$ Millions)	204
Figure 132 Lonza Revenue Share, by Business Segment, 2017 (%)	205
Figure 133 Lonza Revenue, by Region, 2015-2017 (\$ Millions)	206
Figure 134 Lonza Revenue Share, by Region, 2017 (%)	207
Figure 135 Sun Pharmaceutical Revenue, by Business Segment, 2015-2017 (\$ Millions)	210
Figure 136 Sun Pharmaceutical Revenue Share, by Business Segment, 2017 (%)	211
Figure 137 Dr Reddy's Laboratory Revenue, by Business Segment, 2015-2017 (\$ Millions)	214
Figure 138 Dr Reddy's Laboratory Revenue Share, by Business Segment, 2017 (%)	215
Figure 139 Dr Reddy's Laboratory Global Generics Revenue, by Region, 2015-2017 (\$ Millions).....	216
Figure 140 Dr Reddy's Laboratory Global Generics Revenue Share, by Region, 2017 (%).....	217
Figure 141 Dr Reddy's Laboratory PSAI Revenue, by Region, 2015-2017 (\$ Millions)	218
Figure 142 Dr Reddy's Laboratory PSAI Revenue Share, by Region, 2017 (%)	219



About BCC Research

About BCC Research

With our unparalleled 45-year history, BCC Research provides comprehensive analysis of global market sizing, forecasting and industry intelligence, covering markets where advances in science and technology are improving the quality, standard and sustainability of businesses, economies and lives.

BCC Membership

From market sizing and forecasts, to opportunity assessments and competitive analyses, our ever-expanding library gives you the data, insights and intelligence required to ensure your project is a success. Members benefit from ongoing, unlimited access to the category or collections of their choice, and most membership packages pay for themselves within two to three reports being accessed.

Did you buy this report? You may qualify to apply your purchase price towards a full membership. Call 866/285-7215 or email info@bccresearch.com to request a demo.

BCC Custom Research

Our experts provide custom research projects to those working to identify new markets, introduce new products, validate existing market share, analyze competition and assess the potential for products to impact existing markets. With impressive academic credentials and broad and deep knowledge of global industrial markets, our independent analysts and consultants develop the facts, figures, analysis and assessments to inform the decisions that will move your company ahead. Confidential inquiries to: custom@bccresearch.com or 781-205-2429.

DISCLAIMER

The information developed in this report is intended to be as reliable as possible at the time of publication and is of a professional nature. This information does not constitute managerial, legal or accounting advice, nor should it be considered as a corporate policy guide, laboratory manual or an endorsement of any product, as much of the information is speculative in nature. BCC Research and the author assume no responsibility for any loss or damage that might result from reliance on the reported information or from its use.

ISBN: 978-1-62296-765-0
July 2018