Global Biosimilars Outlook - 2019 & beyond

MP Team

Spring 2019

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Advisors

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Executive Summary

- Biosimilars will bring about much deeper market penetration among the patients across economic spectrum with rapidly declining costs, both in developed and emerging markets
  - Market size will multiply with increasing discounts
  - Margins will remain much more robust than the small molecule generics
- With 15+ biologics losing patent by 2020, >70 pharma companies have >200 biosimilars in pipeline globally, to participate in $40B opportunity by 2025
  - First wave biosimilars face growing competition, leaving few opportunities for newcomers
  - Next wave biosimilars too call for a solid foundation, giving first wave competitors a major edge
- Regulatory and payor landscape, especially in the US, is evolving rapidly, with increasing support for biosimilars from multiple stakeholders
  - First mover multinational companies have invested heavily in select biosimilars portfolio
  - Originator companies have put up clever barriers for biosimilar competitors
  - Near term outlook is murky, but ultimate outcome to mirror the evolution of small molecule generics landscape, only faster
- Price competition is already intensifying, with 60+% discounts not uncommon
  - A clear regulatory path to lower registration costs, scale helping reduce manufacturing costs, substitutability guidelines on the horizon, and increasing role of payor groups—all add up to higher discounts
  - A handful of companies with a broad portfolio and global reach, combined with reliable and quality supply will capture a major share of the biosimilars market
- Early acceptance of biosimilars in emerging markets is enabling a select group of biosimilar companies to achieve market position and cash-flow positive operations
- Combining initial emerging market success with much larger developed markets potential a key success requirement in biosimilars space
  - First mover multinational companies with heavy biosimilars investments will present stiff competition, provided they accept competitive pressures

Evolving Biosimilar Opportunity

- Biosimilars are "similar" to the originators' biologics today, but consistent safety and efficacy experience combined with better tools to confirm this similarity will enable regulators to define interchangeability, and allow substitution over the coming decade—even though biologic production and analyses cannot be precisely replicated

- Biosimilars are emerging as one of the most important sectors in the healthcare industry to curb increasing healthcare costs, primarily associated with biologics

  - Biopharma has accounted for nearly one-half of the inflation in healthcare costs in the US, primarily due to the launch of innovative biologics

  - Biosimilars are likely to sell at 80% discount to innovator biologics, lowering the healthcare cost while rapidly expanding their use via biosimilars globally and fostering next wave of innovations at the same time

- Current and future batch of biosimilars can be grouped into three waves:

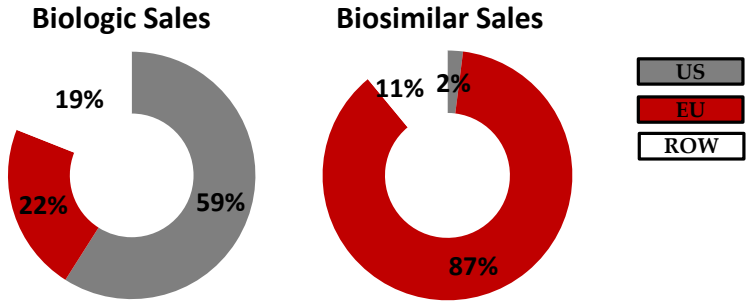
  - Wave 1 biosimilars: Cytokines, growth factors & hormones, such as filgrastim, epoetin alfa, etc.

  - Wave 2 biosimilars: Mostly monoclonal antibodies coming off patent by early 2020s, such as infliximab, tocilizumab, etc.

  - Wave 3 biosimilars: Complex monoclonal antibodies, antibody fragments, antibody drug conjugates (ADCs) and newer technologies going off patent after early 2020s, such as aflibercept, ranibizumab, ustekinumab, etc.

Biosimilar Sales & Market Size

- Biologics sales WW are over $250B
  - ~2% ($5B) of the overall biologics sales were contributed by biosimilars in 2017, which is likely to triple by 2020
  - At least $200B of biologics sales face biosimilar competition, which should amount to at least $40B in biosimilar sales in the near future—even at a 80% discount to the originator's price
- Europe accounts for 87% of global biosimilars sales of $5B, compared to just 2% from the US, even as the US accounts for 59% of branded biologic sales vs only 22% coming from Europe
- Globally, over 200 biosimilars for more than 50 biologics are being developed by about 70 companies in various phases of development
- As many biopharma companies developing biosimilars focus on developed markets, accelerating competition promises to bring prices down considerably
- Over the coming decade, massive unmet demand in emerging markets also promises to offer an attractive opportunity



Source: Company Reports, MP Analysis

Biosimilar Uptake – Current and Future

Region	Regulatory Environment		Access to Biologics		Payor Assessment & Access		Prescriber Acceptance		Patient Acceptance		Biosimilars Presence	
	2019	2021	2019	2021	2019	2021	2019	2021	2019	2021	2019	2021
EU	Established in 2000	Established	◕	◕	◕	◕	◑	◕	◑	◕	50	70+
US	In development	Established	◕	◕	◔	◑	◔	◑	◔	◑	15	30+
Japan	Established in 2007	Established	◕	◕	◑	◑	◔	◕	◔	◕	18	25+
India	Established	Established	◔	◔	◔	◑	◑	◑	◑	◑	60	70+
S. Korea	Established	Established	◑	◑	◕	◕	◔	◕	◑	◕	12	25+
China	In development	Established	◔	◔	◑	◔	◔	◔	◔	◔	0	10+
LATAM	Established	Established	◔	◔	◔	◑	◔	◑	◑	◑	9	15+

- Across European countries, differences exist in biosimilar policies leading to variations in its uptake and divergences in savings from biosimilars use; most countries have established specific supply-side policies for promoting access to biosimilars
- A balanced regulatory framework is evolving, with inclusion of substitutability, along initiatives to increase the update by payors in-parallel
- Strong government promotional measures to use biosimilars, at least in DPC (Diagnostic Procedure Combination payment system) hospitals, will further drive penetration in Japan
- Biosimilar uptake in developed markets such as South Korea will be influenced primarily by payor/government efforts to curb healthcare costs
- Biosimilar uptake in developing markets such as China and India are largely dependent on patient spending power, given the large proportion of out-of-pocket healthcare spend in these countries
- In LATAM, payors are increasingly looking to biosimilars to help curb healthcare expenditure and broaden patient access

Source: Company Reports, MP Analysis

Status/Prospect ◔ Low ◑ Medium ◕ High

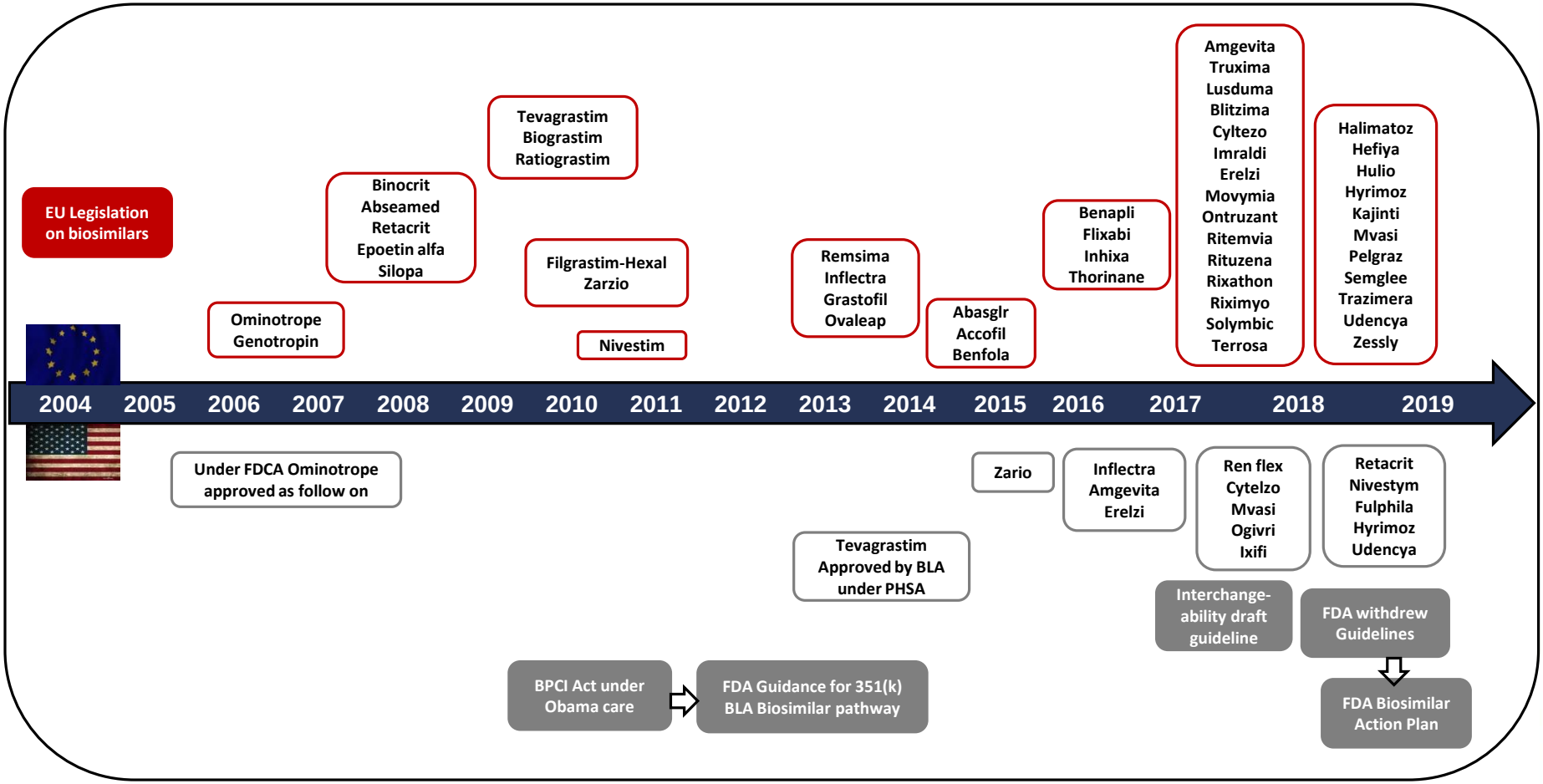
Biosimilars – Evolving Regulatory Pathway

Parameters	Innovator Brands	Biosimilars Today	Substitutable Biosimilar Generic Tomorrow
Clinical Development	Extensive clinical studies- PK/PD and phase I, II and III	At least one clinical study - PK/PD and phase I and III; some cases only phase I	Often only Phase I, after rigorous PK/PD
Indications - Extrapolation	Clinical data required for all indications - extrapolation not allowed	Clinical data required for only one representative indication - extrapolation case by case	Often only Phase I, after rigorous PK/PD, referencing innovator data
Maturing Regulation to Substitutability	-	Demonstrate similarity – no automatic substitution in most developed regions	Demonstrate equivalence - substitution with maturing regulations may be allowed
Manufacturing Evolution	Multiple site changes, including CMOs, watched by innovator deemed identical	Biological process difficult, but equivalence definition per maturing regulations	Mature regulations to yield a clear path to equivalent finished product protocols
Cost of Development	$1B	$100-200m	$10-20m
Time to Development	10+ years	5+ years	2+ years
Potential for Exclusivity	Up to 12 years	Up to 1 year possible	Up to 1 year possible
Discounts to originator price	-	30+%	Up to 80%

The future biosimilars will be more like today's generics where they require baseline clinical studies, lowering the development cost and faster approvals that will continue to accelerate competition leading to lower prices

Source: Company Reports, MP Analysis

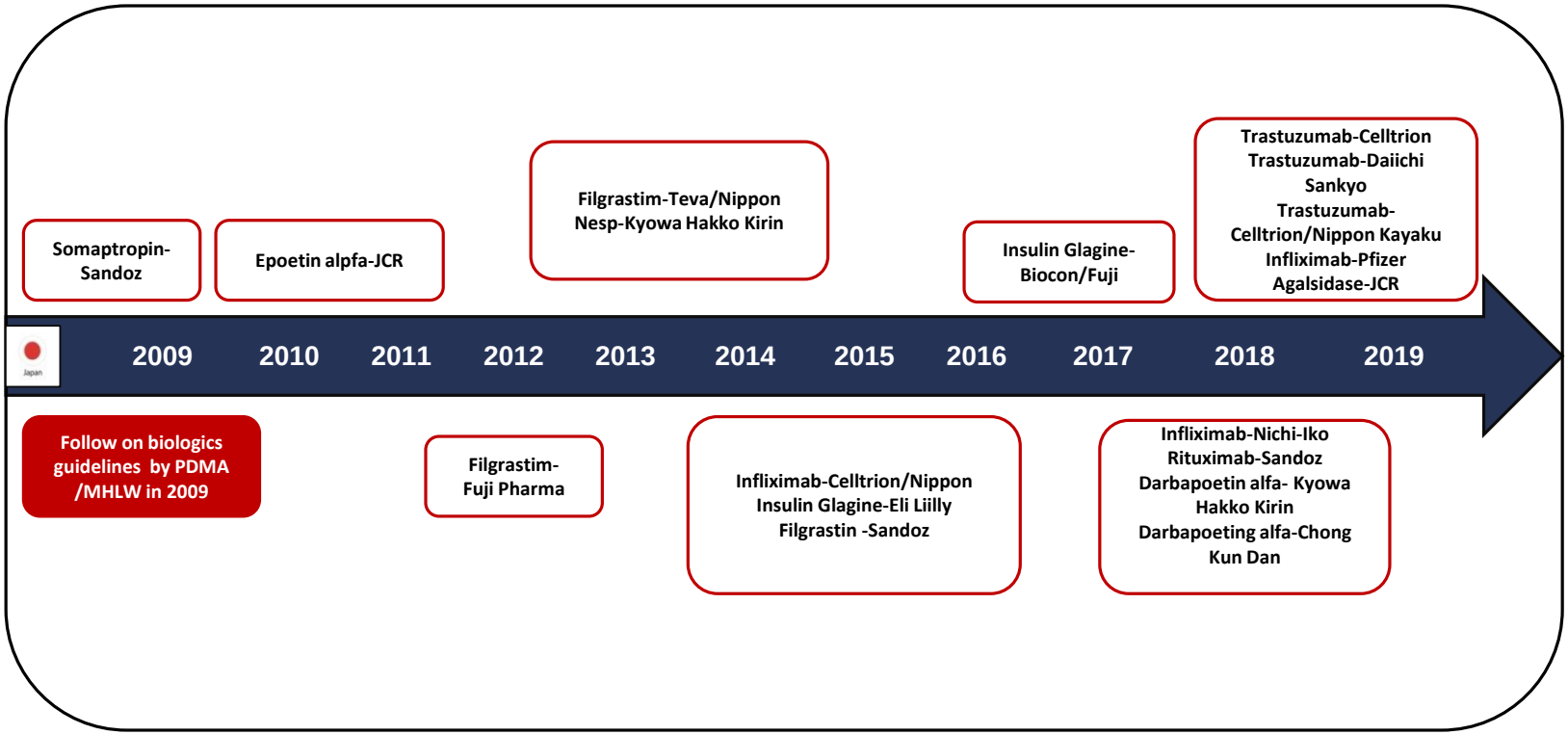
Key Regulatory Milestones in EU vs. US for Biosimilars



Parameters	US	EU
Exclusivity for biologics	4 years data exclusivity plus 8 years market exclusivity from the time of patent issue, total 12 years	8 year data exclusivity from the time of patent issue plus 2 years market exclusivity; additional 1 year market exclusivity for new indication within first 8 years
Approval Standards	FDA regulates interchangeability, switching and substitution whereas substitution is often practiced at pharmacy level	EMA does not regulate interchangeability, switching and substitution

Source: Company Reports, MP Analysis

Key Regulatory Milestones in Japan for Biosimilars



Japan Biosimilars

- PMDA has so far approved 18 biosimilars for 10 biologics from 14 companies
- Biologics have 8 years of data exclusivity in Japan
- Penetration of MAbs in Japan will create a $3.6B opportunity for the pharma companies in the next three years

Source: Company Reports, MP Analysis

Regulatory Milestones for Biosimilars in India, South Korea & China

- In India, biosimilar guidelines were established in 2012 and has some of the biggest and most advanced pipelines, where 60+ biosimilars for 15 biologics by 15+ companies have been approved
  - The first biosimilar in India was approved in 2000, and, with the help of legislation and regulation from the Indian Government, the market has continued to grow since, reaching a value of ~$1B in 2017
  - Partnerships between global pharmaceutical companies and domestic companies are helping to improve the quality of biosimilars marketed in India
- In South Korea, 12 biosimilars for 7 biologics have been approved and >30 are in the pipeline
  - South Korea is expanding manufacturing infrastructure which is likely to account for ~40% of the global biosimilars manufacturing by 2020, having established it as a national priority only in 2012
  - Government invested ~35 % of the national medical R&D budget into biosimilars development from 2012 and has set a goal for domestic biopharmaceutical companies to gain 20% of the global biosimilar market share by 2020
- In February 2015, CFDA in China issued the Technical Guidelines for R&D and Evaluation of Biosimilars, in an attempt to foster the development of the biopharmaceutical industry
  - Due to unclear regulatory policies, no real biosimilar drug has been approved in China so far, however, it is in the process of creating a development, manufacturing and regulatory ecosystem favoring biosimilars
  - Most of the biosimilars are in Phase III development, centered around a set of biologics that includes adalimumab, infliximab, etanercept, rituximab, bevacizumab and trastuzumab

Source: Company Reports, MP Analysis

Regulatory Milestones for Biosimilars in LATAM

- In LATAM, despite idiosyncratic disparities among the countries, 9 biosimilars for 5 biologics from 8 companies have received approval
-
- Biosimilars market is expected to reach $1B in 2020 with Argentina, Brazil, and Mexico to be the highest contributors
- Status of regulatory pathway for some of the countries in LATAM:
  - **Brazil** is unusual in having two regulatory pathways – the 'comparative' pathway and the 'individual development' pathway, both introduced by the National Health Surveillance Agency (ANVISA) in 2010
  - **Argentina** introduced a formal regulatory pathway in 2011 and has been instrumental in establishing the need for rigorous approval standards in Latin America
  - **Mexico** established its biosimilar regulatory pathway in 2012, but this did not officially take effect until early 2015 and now the Mexican regulatory body, COFEPRIS, requires manufacturers of biosimilar products approved before the new regulations to reapply, with all the necessary evidence
  - **Chile** is yet to release biosimilar guidance, but a draft issued in 2011 suggests that Chilean regulators will draw upon the EMA and WHO guidelines
  - **Colombia** issued draft guidelines in 2013, which are yet to be finalized. In the interim, some stakeholders have expressed concern that, although the draft guidelines declare that the required data must show the quality, efficacy, and safety of a biosimilar, there are no specifications as to how these properties should be demonstrated by the applicant

Source: Company Reports, MP Analysis

Early Wave Biosimilars - Competitive Landscape

Biologics	Therapy Area	Approved Biosimilars			Total Approvals until 2018	Marketed Biosimilars			Total Marketed until 2018	Biosimilars Pending Approval			Biosimilars in Phase III			Total Approval anticipated by 2021
		EU	US	Japan		EU	US	Japan		EU	US	Japan	EU	US	Japan	
Etanercept	Rheumatology	2	1	1	4	2	-	1	3	2	-	1	1	1	1	10
Filgrastim	Hematology	8	2	3	13	8	2	3	13	-	2	-	1	1	-	17
Pegfilgrastim	Hematology	5	2	-	7	5	1	-	6	1	-	-	1	1	-	10
Epoetin Alfa/Zeta	Hematology	5	1	3	9	5	-	3	8	-	-	-	1	-	-	10
Rituximab	Auto Immune Diseases	6	1	1	8	6	-	1	7	1	1	1	6	3	1	21
Trastuzumab	Oncology	3	2	3	8	3	-	3	6	-	-	-	3	1	-	12
Adalimumab	Inflammation	8	3	-	11	8	-	-	8	2	1	-	5	4	3	26
Bevacizumab	Ophthalmology, Oncology	1	1	1	3	1	-	-	1	1	1	1	6	4	3	19
Infliximab	Auto Immune Diseases	4	3	3	10	4	2	3	9	1	-	-	1	2	-	14
Total		42	16	15	73	42	5	13	60	8	5	3	23	18	8	139

Key Inferences

- Though US and Japanese cos were late to enter biosimilar space, they have focused on the right set of biosimilars for development
- For biosimilars like rituximab, adalimumab and infliximab, some of the global companies are strategically reconsidering their launch in US or EU, based on the competition for e.g. Pfizer has decided not to launch its second infliximab biosimilar –Ixifi in the US
- As early wave biosimilars witness intense competition, it is timely to consider next set of opportunities

Source: Company Reports, MP Analysis

Three examples to give a glimpse our ongoing in-depth analysis

- Adalimumab
  - Patent expiry – 2018
  - High competitive intensity across all the geographies
- Etanercept
  - Patent expiry – 2028 (US) and 2015 (EU)
  - Moderate competitive intensity in EU and low in the US
- Ranibizumab
  - Patent expiry – 2020 (US) and 2022 (EU)
  - Low competitive intensity across all geographies
  - Included in the pipeline of several companies at early development stage

Humira - Adalimumab Witnesses High Competitive Intensity across the US & EU

Parameters	US	EU	Other
Originator Sales (2017, USD Mn)	• 12361 (Y-o-Y growth - 18.5%)	• 6066 (Y-o-Y growth - 7%)	• NA
Marketed	• -	• Hefiya(Sandoz) • Imraldi (Samsung – Bioepis) • Cyltezo, 2017 (BI) • Amjevita, 2016 (Amgen) • Hyrimoz (Novartis AG/Sandoz) • Solymbic (Amgen) • Hulio(Mylan) • Halimatoz(Sandoz)	• Torrent (India) • Cinnagen (Iran) • Zydus (India)
Approved biosimilar	• Cyltezo, 2017 (BI; ongoing litigation) • Amjevita, 2016 (Amgen; launch in Jan 2023 • Novartis AG/Sandoz • Samsung – Bioepis	• -	• Cylzeto (APAC, LTAM, CIS, Russia) • Imraldi (APAC) • Hyrimoz (Novartis AG/Sandoz) Russia
Pending approval	• Fujifilm/KHK • Sandoz	• Fujifilm/KHK • Sandoz • Fresinius	• Fujifilm/KHK (LATAM, CIS, Russia) • Sandoz (APAC, CIS, Russia) • Fresinius (Canada)
PhIII	• Biocon/Mylan • Coherus • Momenta • Pfizer	• Biocon/Mylan • Pfizer • Momenta • Fresenius	• LG/Mochida (APAC, Japan) • Momenta (Canada) • Pfizer (APAC, CIS, Russia, LATAM, Japan, Canada) • AbbVie (Japan) • Shanghai Henlius Biotech(China)
PhII	• -	• 180 Therapeutics	• Biocad/ Biotoscana (CIS, Russia)
Ph I	• Momenta	• Momenta • Biocon • Outlook Therapeutics	• Dong-A/Meiji (Japan) • Oncobiologics (Canada) • Walwax Biotech • Alphamab • Outlook Therapeutics(Mexico)
Total	15	20	24
Comments	• Amgen and Sam – Bio did a settlement with Abbvie during patent litigation for adalimumab launch in US and EU • Litigation of BI with Abbvie has not come to a settlement for US and EU market • In 2017 (Q3), BI has initiated a phase I interchangeability study in the US; VOLTAIRE-X study is being conducted in 240 chronic plaque psoriasis patients and the results are expected in Q3 of 2019		

Source: Company Reports, MP Analysis

Enbrel - Etanercept Witnesses Moderate & Low Competitive Intensity in EU & the US Respectively

Parameters	US	EU	Other
Originator Sales (2017, USD Mn)	• 5433 (Y-o-Y decline - 9%)	• 2452 (Y-o-Y decline - 15%)	• NA
Marketed	• -	• Brenzys (Samsung – Bioepis) • Erelzi (Sandoz)	• Amega Biotech (LATAM) • Probiomed (Mexico) • Nanogen Biopharma (APAC) • Harvest Moon Pharma (LATAM) • Cipla (LATAM) • Samsung–Bioepis (Canada, APAC) • Sandoz (Canada) • Aryogen Pharma(Iran) • Hanwa Chemical (Korea) • Erelzi (Sandoz) • LG lifesciences(Japan) • Intas(India) • Taj Pharma(India)
Approved biosimilar	• Erelzi (Sandoz)		• Mycenax Biotech (APAC, Japan)
Pending approval		• Lifmior (Pfizer) • Lupin/Yoshindo	• LG Life/Mochida (APAC) • Lupin/Yoshindo (APAC)
PhIII	• Coherus	• Coherus	• Coherus (APAC MENA, Africa, Japan, Canada) • Lupin/Yoshindo (Japan) • Hanwa/Merck (APAC) • Simcere(China) • Zhejiang Hisun(China)
PhII	• -	• Samsung Bioepis	• Biocad/ Biotoscana (CIS, Russia) • Genemem Biotech (China)
Ph I	• -	• -	• Sichaun Clover(China)
Total	2	7	24
Comments	• Etanercept biosimilar is expected to launch in the US either in 2019 or 2028 depending of litigation outcome • Etanercept biosimilar of Sam-Bio, launched in 2016 in EU, attained annual sales of USD 370 Mn • It is critical to watch the biosimilar development of mid-sized players like Coherus and Lupin in EU region • IP strategy will be important in the US market due to high unit price (US vs EU vs Japan – USD 996 vs 226 vs 161) • Currently, Sandoz and Coherus litigations are ongoing against Amgen for the US market • Lupin/Yoshindo JV conducted PhIII study in 500 rheumatoid arthritis patients across Japan, EU and India • In 2017, Amgen launched Enbrel Mini, which utilizes new formulation associated with lower injection site pain		

Source: Company Reports, MP Analysis

Lucentis - Ranibizumab Biosimilars Witness Minimal Competition with Few Cos in Phase III of Developments

Parameters	US	EU	Other
Originator Sales (2017, USD Mn)	• 1435	• 1880	
Marketed	• -	• -	• Biocure Pharm (S. Korea)
Approved biosimilar	• -	• -	• -
Pending approval	• -	• -	• -
PhIII	• Samsung Bioepis	• Formycon • Samsung Bioepis	• Intas (India) • RLS (India) • Samsung Bioepis (Russia)
PhII	• -	• -	• Pfenex/Hospira (APAC)
Ph I	• -	• -	• BioCND/Qilu (China) • Lupin
Preclinical	• Coherus, Chong Kun Dang Pharma, Mabion SA, Ascendis Pharma, Paras Biopharma Finland, PlantForm Corporation, Siam bioscience, Samsung Bioepis, Xbrane biopharma (Asia), Harvest Moon Pharma		
Total	1	2	7
Comments	• In EU, Formycon started PhIII study in 2016 and is expected to launch the by 2020 • Samsung – Bioepis launched a global PhIII trial in 2017 which is expected to complete by 2019 • In EU, the compound patent expires in 2018 while the SPC patent expires in 2022 • In US, the patent is expected to expire in 2020		

Source: Company Reports, MP Analysis

Biosimilar Companies in Developed Markets

Country/Region

EU		US		Japan	
Mabion SA	7	Mylan	11	Gene Techno Science	9
Alvotech	6	Pfenex	7	Nichi-iko	6
Pol Pharma	5	Momenta	6	Daiichi Sankyo	4
Stada Arzneimittel Ag	3	Coherus	5	Meiji Seika Pharma*	3
Gedeon Richter	3	Merck Sharp & Dohme	5	Kyowa Hakko Kirin	1
Stada Arzneimittel Ag	3	Amgen	4	Mochida	1
Xbrane	3	Pfizer	4	Yoshindo	1
Formycon	3	Samsung Bioepis	3	Fuji Pharma	1
Fresenius	2	Apobiologix/Apotex	2	JCR	1
Accord Healthcare	1	Adello Biologics	2	Kissei	1
Hexal Ag	*	Eli Lily	1	Nippon Kayaku	*
Nanolek	*	Boehringer Ingelheim	1	UMN Pharma	*
Sandoz GmbH	*	Outlook Therapeutics	1	Aska Pharma	*
Medice Arzneimittel	*	Teva	*	Towa	*
Ratiopharma GmbH	*			Toyobo	*
Samsung Bioepis	*			Nipro Pharma*	*
Tech Dow Europe	*			Sawai	*
Pharmathen SA	*			Mitsubishi Tanabe	*
Cinfa Biotech	*			Fujifilm Pharma*	*
Egis	*			Taiyo	*
Total	**31**	**Total**	**51**	**Total**	**28**

Note: The number on the right indicates the number of biosimilars in development pipeline for each company
* Indicates that the pipeline is undisclosed

Source: MP Analysis

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Selected Biosimilar Companies in Developed Market

Region	Company Name	Current Status of Biosimilar Pipeline
US	Pfizer	▪ Active interest and success of early entry in the US (Remicade infliximab launched) ▪ It will need full basket of biosimilars to encash strong front end presence globally
	Apotex	▪ Active interest in partnering for biosimilar products in oncology ▪ Current pre-clinical/clinical pipeline comprises of filgrastim, pegfilgrastim, Epoetin alfa, bevacizumab, rituximab and trastuzumab, but not the four priority RLS moleules
	Coherus	▪ Leading biosimilar company with recent approval of pegfilgrastim biosimilar Udenyca by FDA and EMA ▪ With current focus in Oncology and Ophthalmology, they have adalimumab, etaernacept, ranibizumab and aflibercept in their biosimilar pipeline
EU	Egis (Hungary)	▪ Egis got into a partnership with Celltrion to launch 8 biosimilars for CIS/certain EU markets , but not RLS four molecules ▪ RLS portfolio will facilitate the expansion of its portfolio
	Mundipharma (UK)	▪ Key TA focus includes pain, oncology, respiratory and addiction therapy ▪ It has launched rituximab and infliximab biosimilars in EU ▪ RLS portfolio will facilitate the expansion of its portfolio, especially in oncology and respiratory space
	Formycon (Germany)	▪ Formycon is a leading developer of biosimilar drugs and has partnered with three German companies (Bioeq, Santo Holding GmBH and Aristo Pharma GmBH) ▪ Current pipeline includes Lucentis, Stelara and Eylea
Japan	Gene techno science	▪ Gene Techno Science developed filgrastim biosimilar (in-licensed from Dong-A to develop for JP & other global markets) with Fuji Pharma ▪ Other pipeline biosimilars are peg-filgrastim, bevacizumab, adalimumab, palivizumab and darpoetin alfa
	Meiji Seika Pharma	▪ Trastuzumab and adalimumab biosimilar are in the pipeline; in September 2011, they concluded a comprehensive long-term agreement with Dong-A Pharma (S-Korea) for biosimilars ▪ MSP aims to sell three kinds of biosimilars including trastuzumab by 2020. MSP decided to boost MR numbers to 900 in FY2014 from 770 to promote "fusion strategy" to strengthen its new and generic drug business
	Fuji Film Kyowa Kirin Biologics	▪ Adalimumab and bevacizumab biosimilar in the pipeline ▪ Company had aimed to start clinical trials of one biosimilar every year after 2014 and intends to talk with other companies for collaborations

Source: MP Analysis

Biosimilar Companies in RoW

Country/Region

India		China		South Korea		LATAM	
Reliance Life Sciences	20	AlphaMab	19	Dong-A Socio Holdings	7	Cristalia Lab	3
Zydus Cadila	11	3SBio Inc	9	Alteogen Inc	6	Pharma Praxis	2
Dr. Reddy's	11	Zhejiang Huahai	8	Aprogen Inc	6	Farmacore Biotec	2
Biocon	7	Shanghai Henlius Biotech	6	Celltrion Inc	5	Axis Biotec Brasil	1
Cipla	6	Shanghai CP Guojian	6	LG Life Sciences	5	Eurofarma	1
Lupin	5	Bio-Thera Solutions	6	ISU ABXIS Inc	4	LIBBS	1
USV	5	Zhejiang Hisun	5	BIOCND	4	Bionovis SA	*
Intas	2	Luye Pharma Group Ltd	4	Schnell Biopharma	4	Blau Farma	*
Glenmark	1	Jiangsu T-mab	3	Samsung Bioepis	3	EMS	*
Hetero drugs	1	Qilu Pharmaceutical	3	Daewoong	2		
Emcure	*	Walvax Biotechnology	3	Dong-A ST	1		
Genex Pharma	*	Innovent Biologics Inc	2	BL&H Co	*		
Panacea biotech	*	Xiamen Amoytop	1	HanAll BioPharma	*		
Camus Pharma	*	Jiangsu Hengrui	1	Biocure Pharm	*		
		Changchun ChangSheng Gene	*				
Total	**69**	**Total**	**76**	**Total**	**47**	**Total**	**10**

Note: The number on the right indicates the number of biosimilars in development pipeline for each company
* Indicates that the pipeline is undisclosed

Source: MP Analysis

Selected Biosimilar Companies in RoW

Region	Company Name	Current Status of Biosimilar Pipeline
India	Intas	▪ Intas becomes the first Indian company to launch a biosimilar in highly regulated markets like EU, US and Japan ▪ Intas is also the only company from India to have two of its products, filgrastim and peg-filgrastim filed for registration in the US, through its collaboration partner ▪ Has more than 8 biosimilars in the pipeline
	RLS	▪ Biopharmaceutical company with presence in domestic as well as emerging markets ▪ It has 15 biosimilar approved and marketed across 35 countries and looking for pipeline expansion
China	Shanghai CP Guojian	▪ Focuses on development and commercialization of antibody therapeutics ▪ Presence in several emerging markets and actively looking for partnership ▪ Daclizumab and eternacept biosimilars marketed in China and trastuzumab and ipilimumbai biosimilars in pipeline
	3SBio Inc	▪ Biopharmaceutical company with presence in domestic as well as emerging markets ▪ Its eternacept biosimilar is approved in 10 countries and looking for pipeline expansion
S. Korea	Biocure Pharm	▪ The company focuses on developing biosimilars and recombinant proteins. ▪ Launched biosimilars of Neupogen, Aranesp and Lucentis ▪ Also present in MENA and LATAM regions with JV/partnerships
	Dong-A Socio Holdings	▪ Pharma sector of this group focuses on biologics and biosimilars in arthritis, multiple sclerosis, hemophilia and cancer ▪ They are developing biosimilars for domestics as well as various developed and emerging markets
LATAM	Ache/ Bionovis	▪ Wishes to expand biosimilar portfolio in Brazil and LATAM region ▪ It has co-development partnership with Fresenius/Merck KGaA for 8 biosimilar programs for Brazil market
	Blau Farmaceutica	▪ A leading pharma company in the LATAM region ▪ Recently, it entered the biosimilar space and will be planning to expand its portfolio

Source: Company Reports/Website, MP Analysis

Key Biosimilar Partnerships (2017-2018)

Recipient-Acquirer	Molecules	Geography
Biocon, Ltd.-LIBBS Farmaceutica Ltd	trastuzumab	Brazil
Xbrane Biopharma AB-China Resources Pharmaceutical Group Limited	Spherotide	China
Amgen, Inc.-Simcere Pharmaceutical Group	trastuzumab, rituximab, infiximab, cetuximab	China
Samsung Bioepis Co. Ltd.- 3SBio, Inc.	Bevacizumab plus other biosimilars	China
Prestige BioPharma Pte Ltd-Alvogen, Inc.	trastuzumab	Europe
FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.-Mylan N.V.	adalimumab	Europe
Laboratorios Farmaceuticos ROVI, S.A.-BIOGARAN|Les Laboratoires Servier	enoxaparin	France
Formycon AG-Santo Holding (Deutschland) GmbH	aflibercept	Germany
Lupin Limited-Nichi-iko Pharmaceutical Co., Ltd.	etanercept	Japan
Celltrion Healthcare, Inc.|Celltrion, Inc.-Nippon Kayaku Co., Ltd.	infliximab	Japan
Celltrion Healthcare, Inc.|Celltrion, Inc.-Hikma Pharmaceuticals PLC	infliximab	Middle East and Africa
Cinfa Biotech -Mundipharma	pegfilgrasrtim	United States
Insud Pharma (formerly Chemo Group)|Mabxience-Amneal Pharmaceuticals, Inc.|Amneal Pharmaceuticals, L.L.C.	bevacizumab	United States
Lupin Limited-Mylan N.V.	etanercept	Asia-Pacific,Australia,Europe,Middle East and Africa,New Zealand,South and Central America
AbbVie, Inc.-Pfizer, Inc.	Adalimumab launch	Asia-Pacific,Europe,Middle East and Africa,North America,South and Central America
Revance Therapeutics, Inc.-Mylan Ireland Limited|Mylan N.V.	onabotulinumtoxinA	Asia-Pacific,Europe,Middle East and Africa,North America,South and Central America
Xbrane Biopharma AB-STADA Arzneimittel AG	ranibizumab	Asia-Pacific,Europe,Middle East and Africa,United States

- In the past two years, about 70 partnerships have taken place in the biosimilar market globally
- Partnerships/Collaborations have been the key driver for a company's success in biosimilars space

Source: Company Reports, MP Analysis

The Way Forward

- With an opportunity of at least $40B in biosimilar sales in the near future, and $100B within the decade, this high margin biosimilars growth opportunity can also help accelerate global reach
- In such a dynamic landscape, no single biosimilar company has been able to thrive without collaborating in some way or the other
  - Where time is of the essence, rapidly trading- off resources based on dynamic market conditions and partnering to capture opportunities is the way forward
  - A more attractive approach may be to find a strategic partner, particularly when one partner has expertise in contracting/tendering and access to key channels, and the other brings development + manufacturing strength
  - Presence in emerging markets would be of equal importance, if not more, than developed markets, when it comes to scale and revenues to build cost-effective market access to fully leverage initial large investments
- New entrants can prove their prudence of not being among the first with bold yet prudent collaboration with one of the short list of established biosimilars companies, helping accelerate combined portfolio and geographic reach to become one of the six companies likely to dominate
  - The new entrants in biosimilars space have already missed the bus for the first wave of biosimilars and therefore, should focus on the next wave of products
  - For wave 2 and 3 biosimilars, right selection of products, therapy area and region will be instrumental in achieving long term success—ideally with a partner so as to not to reinvent the wheel
  - It is the right time to enter the biosimilars space with the next wave of products as clarity in regulatory guidelines and increasing adoption for biosimilars globally continue to make this a timely opportunity

Partnering Opportunities with MP Group

With about 3 decades of diverse experience and integrated perspective in domestic and global BioPharma industry, MP Group has capabilities to support your team in the following key areas –

- **Identify unique and creative domestic and global investment opportunities**
- **Deep-dive assessment of specific opportunities**
- **Assessment and monitoring current investment portfolio (equity/non-equity)**
- **Market and product portfolio due diligence**
- **Technical due diligence of the target investment opportunity**
- **Commercial and technical feasibility studies**

We invite you to write to us -

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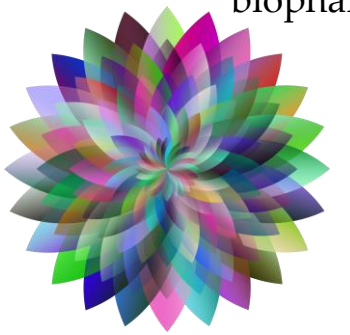
Who We Are

GLOBAL EXPERIENCE

Integrated global perspective anchored around 29 years of biopharmaceutical experience

OUR TEAM

Small and nimble—with industry experience, financial knowhow, scientific expertise and a dash of common sense



BUILDING RELATIONSHIPS

With a worldwide network and lasting friendships, we have built a community of business leaders and science experts to inform our work

WELL GROUNDED

Our globally integrated analysis has identified opportunities early—from NCEs to biosimilars, generics to specialty pharma—which we have helped implement, broadening global growth choices for senior managements

GROWTH AT A FAIR VALUE

As an extension of the management team, we help cross-fertilize actionable ideas

MP Team's Global Network
Deep roots at every level of major biopharma markets

	No of Companies* Retained MPA from 'Top 10' group	No of mid-cap, small companies worked/ well-connected with
Global Pharma (US/Eu)	4/10	100+
Indian	8/10	~100
Japan	3/10	70+
ROW	n/a	~100

- ✓ Retained by senior managements from across the globe
- ✓ Also robust connections with – API, CRAM, CRO, Biotech/Biosimilar, PE, VC and angle investors companies in all geographies
- ✓ Good access to ~all medical specialists, bureaucrats, academia

* At top management level

LANDMARK DEALS IN INDIA CONCEPTUALISED AND EXECUTED BY MP TEAM

1st NCE licensed-out from India (Dr. Reddy's balaglitazone out-licensed to Novo Nordisk)

1st Indian company acquiring major unit in the USA (Sun Pharma acquires Caraco Pharma)

Largest pharma deal of India Daiichi Sankyo acquires Ranbaxy

1st Indian Company making alliance with an MNC for NCE manufacturing (JV between Altana and Zydus Cadila to manufacture 'on patent' pantoprazole)

1st Indian company investing in US Biotech (GVK Bio acquires Aragen Biosciences in the US)

Major deal where an MNC partner buy-outs its Indian partner (Astra Zeneca buys out Astra-IDL, A Hinduja Group Company)

Largest divestment by MNC in India (Brand divestment of Solvay to Indoco Remedies and Alembic Pharma)

1st strategic entry by an Indian company in Japan through brand acquisitions (Sun Pharma acquired 14 long listed products from Novartis, Japan)

First Indian co investing in innovation with direct MNC link (Piramal acquired Hoechst R&D center)