



The BPCIA at 10

Where are we now and where are we heading?

Focus on Pharma 2019

Sterne Kessler Goldstein & Fox P.L.L.C.

October 25, 2019

Technical Minds. Legal Muscle.

Panelists

- Moderator: **Tim Shea** – Director at Sterne, Kessler, Goldstein & Fox P.L.L.C.
- **Paul Golian** – Vice President & Assistant General Counsel at Bristol-Myers Squibb
- **Chandrika Vira** – Director at Sterne, Kessler, Goldstein & Fox P.L.L.C

Best Selling Drugs of 2018

Product	2018 Sales	2017 Sales	BLA Approval Date	351(k) Apps Can be Filed *	351(k) Apps Can be Approved *	
Humira	19.936	18.427	12/31/2002	12/31/2006	12/31/2014	BLA
Eliquis	9.872	7.395	12/28/2012			NDA
Revlimid	9.685	8.187	12/27/2005			NDA
Opdivo	7.57	5.763	12/22/2014	12/22/2018	12/22/2026	BLA
Keytruda	7.17	3.809	9/4/2014	9/4/2018	9/4/2026	BLA
Enbrel	7.126	7.885	11/2/1998	11/2/2002	11/2/2010	BLA
Herceptin	6.981	7.013	9/25/1998	9/25/2002	9/25/2010	BLA
Avastin	6.847	6.686	2/26/2004	2/26/2008	2/26/2016	BLA
Rituxan	6.75	7.298	11/26/1997	11/26/2001	11/26/2009	BLA
Xarelto	6.589	6.234	11/4/2011			NDA
Eylea	6.551	5.83	11/18/2011	11/18/2015	11/18/2023	BLA
Remicade	5.908	7.152	8/24/1998	8/24/2002	8/24/2010	BLA
Prevnar 13	5.802	5.601	12/31/2011	12/31/2015	12/31/2023	BLA
Stelara	5.156	4.011	9/25/2009	9/25/2013	9/25/2021	BLA
Lyrica	4.97	5.065	12/30/2004			NDA

Second Wave of Biosimilar Challenges?

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Humira	19.936	18.427	12/31/2002	12/31/2006	12/31/2014	BLA
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Stelara	5.156	4.011	9/25/2009	9/25/2013	9/25/2021	BLA

US Biosimilar Approvals

(<https://pink.pharmaintelligence.informa.com/datasets/review-pathways/biosimilars>)

Sponsor	Biosimilar Product	Reference Product	US Commercial Status	US Regulatory Status	Submission Dates
Sandoz	Filgrastim-sndz (approved as Zarxio)	Neupogen	Launched	Approved 2015-03-06	2014-05-08
Celltrion and Pfizer (Hospira)	Infliximab-dyyb (approved as Inflectra)	Remicade	Launched	Approved 2016-04-05	2014-08-08; Resubmitted 2015-10-15 after 06-08 CRL
Apotex	Pegfilgrastim	Neulasta	Unapproved	Complete response letter likely 2015-08 to 2015-09	2014-10 to 2014-11
Apotex	Filgrastim (to be called Grastofil)	Neupogen	Unapproved	Complete response letter likely 2015-10	2014-12
Pfizer (Hospira)	Epoetin alfa-epbx (approved as Retacrit)	Epogen/ Procrit	Launched	Approved 2018-05-15	2014-12-16; Resubmitted 2017-11-17 after 06-21 CRL; Resubmitted 2016-12-22 after 10-16 CRL
Sandoz	Etanercept-szss (approved as Erelzi)	Enbrel	Not Launched	Approved 2016-08-30	2015-07-30

US Biosimilar Approvals

Sponsor	Biosimilar Product	Reference Product	US Commercial Status	US Regulatory Status	Submission Dates
Sandoz	Pegfilgrastim (LA-EP2006)	Neulasta	Unapproved	Pending-2019-10 or earlier	2015-09; Resubmission announced 201 following 2016-06 CRL
Amgen	Adalimumab-atto (ABP 501; approved as Amjevita)	Humira	Settlement with Abbvie; eligible to launch 2023-01-31	Approved 2016-09-23	2015-11-25
Samsung Bioepis and Merck	Infliximab-abda (SB2; approved as Renflexis)	Remicade	Launched	Approved 2017-04-21	2016-03
Coherus BioSciences	Pegfilgrastim-cbqv (CHS-1701, approved as Udenyca)	Neulasta	Launched	Approved 2018-11-02	2016-08-09; Resubmitted 2018-05-03 after 06-09 CRL
Boehringer Ingelheim	Adalimumad-abdm (BI 695501; approved as Cyltezo)	Humira	Settlement with Abbvie; eligible to launch 2023-07-01	Approved 2017-08-25	2016-11

US Biosimilar Approvals

Sponsor	Biosimilar Product	Reference Product	US Commercial Status	US Regulatory Status	Submission Dates
Amgen and Allergan	Bevacizumab-awwb (ABP 215; approved as Mvasi)	Avastin	Launched 2019-07	Approved 2017-09-14	2016-11
Mylan and Biocon	Trastuzumab-dkst (MYL-14010; approved as Ogivir)	Herceptin	Settlement with Genentech; launch date undisclosed	Approved 2017-12-01	2016-11
Mylan and Biocon	Pegfilgrastim-jmdb (MYL-1401H; approved as Fulphila)	Neulasta	Launched	Approved 2018-06-04	2016-12-09; Resubmission 2017-12-04 after 10-06 CRL
Pfizer	Infliximab-qbtx (PF-06438179; approved as Ixifi)	Remicade	No plan to launch	Approved 2017-12-13	2017-02-13
Teva and Celltrion	Rituximab-abbs (CT-P10; approved as Truxima)	Rituxan	Settlement with Genentech; launch date undisclosed	Approved 2018-11-28	2017-04-28; Resubmission 2018-05-29 after 02-28 CRL

US Biosimilar Approvals

Sponsor	Biosimilar Product	Reference Product	US Commercial Status	US Regulatory Status	Submission Dates
Samsung Bioepis	Etanercept-ykro (SB4, approved as Eticovo)	Enbrel	Not launched	Approved 2019-04-25	2017-05-25; Resubmission 2018-10-25 after 05-23 CRL
Teva and Celltrion	Trastuzumab-pkrb (CT-P6, approved as Herzuma)	Herceptin	Settlement with Genentech; launch date undisclosed	Approved 2018-12-14	2017-05-25; Resubmission 2018-06-15 after 03-30 CRL
Pfizer	Trastuzumab-qyyb (PF-05280014, approved as Trazimera)	Herceptin	Settlement with Genentech; launch date undisclosed	Approved 2019-03-11	2017-06-22; Resubmission 2018-09-28 after 04-20 CRL
Adello Biologics (now Kashiv Biosciences)	Filgrastim	Neupogen	Unapproved	Complete response letter likely; no update since 2018-05 user fee goal	2017-07

US Biosimilar Approvals

Sponsor	Biosimilar Product	Reference Product	US Commercial Status	US Regulatory Status	Submission Dates
Sandoz	Rituximab (GP2013, also known as Rixathon)	Rituxan	Product development discontinued	Discontinued 2018-11 after complete response letter announced 2018-05-02	2017-07
Amgen and Allergan	Trastuzumab-anns (ABP 980, approved as Kanjinti)	Herceptin	Launched 2019-07	Approved 2019-06-13	2017-07-28; Resubmission 2018-12-2 after 05-25 CRL
Pfizer	Filgrastim-aafi (approved as Nivestym)	Neupogen	Launched	Approved 2018-07-20	2017-09
Samsung Bioepis and Merck	Trastuzumab-dttb (SB3, approved as Ontruzant)	Herceptin	Settlement with Genentech; launch date undisclosed	Approved 2019-01-18	2017-10
Sandoz	Adalimumab-adaz (GP2017, approved as Hyrimoz)	Humira	Settlement with Abbvie; eligible to launch 2023-09-30	Approved 2018-10-30	2017-10-30

US Biosimilar Approvals

Sponsor	Biosimilar Product	Reference Product	US Commercial Status	US Regulatory Status	Submission Dates
Pfizer	Bevacizumab-bvzr (PF-06439535, approved as Zirabev)	Avastin	Launch planned in Q4 2019	Approved 2019-06-27	2018-06
Samsung Bioepis	Adalimumab-bwwd (SB5, approved as Hadlima)	Humira	Settlement with Abbvie; eligible to launch 2023-06-30	Approved 2019-07-23	2018-07
Pfizer	Rituximab-pvvr (PF-05280586, approved as Ruxience)	Rituxan	Not announced	Approved 2019-07-23	2018-07
Tanvex BioPharma	Filgrastim (TX-10)	Neupogen	Unapproved	Complete response letter announced 2019-09-25	2018-10-01 (announced)
Amgen	Infliximab (ABP-710)	Remicade	Unapproved	Pending- 2019-12-17 or earlier	2018-10-01 (announced)

Types of Patents Being Asserted in Biosimilar Litigations

- Humira[®]:
 - Methods of treatment
 - Formulation
 - Methods of making
 - Dosing regimens
 - Purification
 - Alternative patient dosing
- Avastin[®]:
 - Method of inhibition
 - Purification
 - Methods of treatment
 - Methods of making

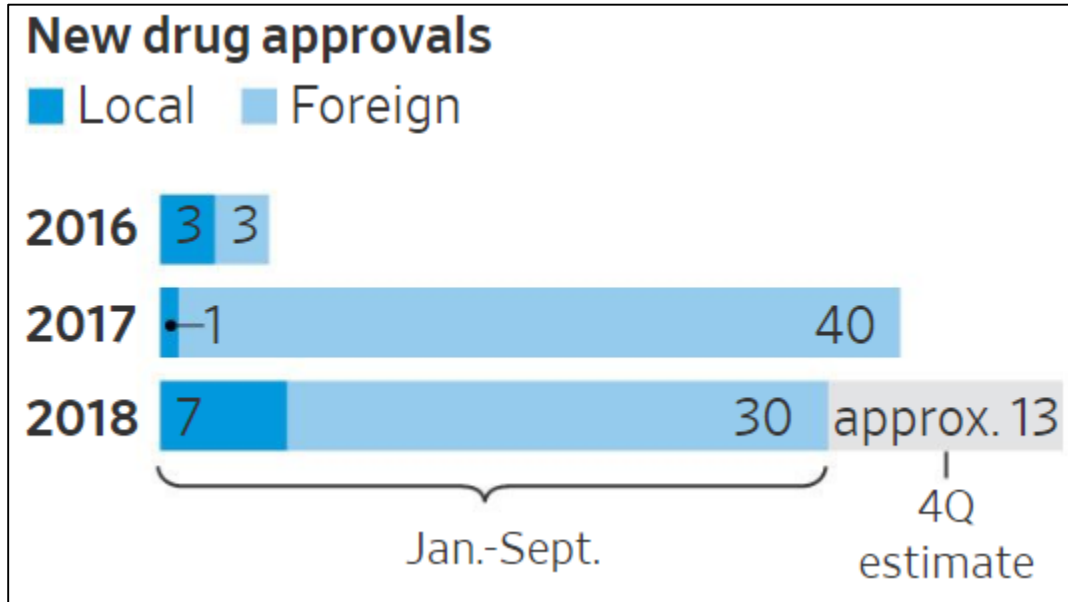
Types of Patents Being Asserted in Biosimilar Litigations con't

- Herceptin[®]:
 - Biomarkers
 - Methods of treatment
 - Purification
 - Dosing
 - Alternative dosing
 - Methods of making

Labeling Issues

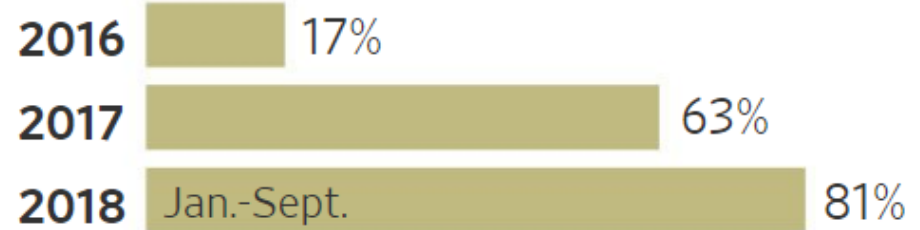
- **Skinny Labeling**: the practice of follow-on drug manufacturers seeking approval for some, but not all, of the indications for which the branded drug has been approved.
- **Indication Extrapolation**: the approval of a biosimilar for diseases or conditions for which it has not been studied based on its similarity to an approved, innovator biological medication

China

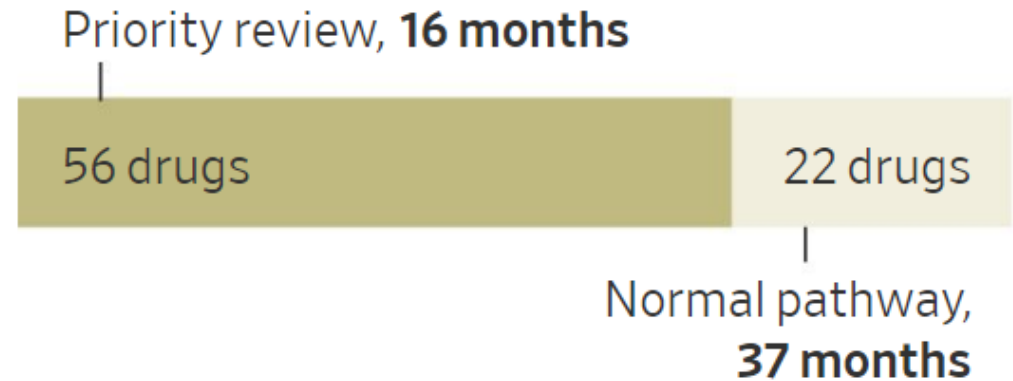


<https://www.wsj.com/articles/big-pharma-wins-drug-approval-in-china-ahead-of-west-for-first-time-11545137592>

Approvals given priority review



Average review time, in months, of 78 drug approvals since Jan. 1, 2017



Closing Thoughts

- Pace of innovation
- Disruptive technologies
- Me-toos
- Biobetters
- Pricing pressures
- Commodity market
- Patent eligibility
- Belief in the patent system
- Personalized medicine
- Domestic versus foreign
- Judges
- Patent offices

QUESTIONS?