

TECH SCAN

BIOSIMILARS



WHERE MIND MEETS MARKET

The landscape of biologic medicines is undergoing a significant transformation with the introduction of biosimilars. These products are set to revolutionize healthcare by offering more cost-effective alternatives to existing biologics, which are often expensive and inaccessible to many patients. The emergence of biosimilars arises in anticipation of the impending expiration of patents for several blockbuster biologic drugs, opening the door for competition and innovation.

Patents in the biosimilar

field cover a wide array of innovations, from novel production processes to unique formulations that maintain the therapeutic efficacy of the reference product. These patents are crucial for protecting the intellectual property of developers and ensuring a competitive market that benefits consumers.

The collaboration between regulatory bodies and biosimilar developers is key to navigating the complex approval process. This partnership ensures that biosimilars meet the high standards of safety, efficacy, and quality required for market entry.

INNOVATION TIMELINE

2006

Somatropin, the first biosimilar approved in Europe, becoming the world's first biosimilar



2015

Zarxio, the first biosimilar in the USA approved by the US FDA



2021

First interchangeable biosimilar approved in the USA



2012

India approved rituximab, the first biosimilar monoclonal antibody



2018

Advancements in analytical techniques for biosimilar development

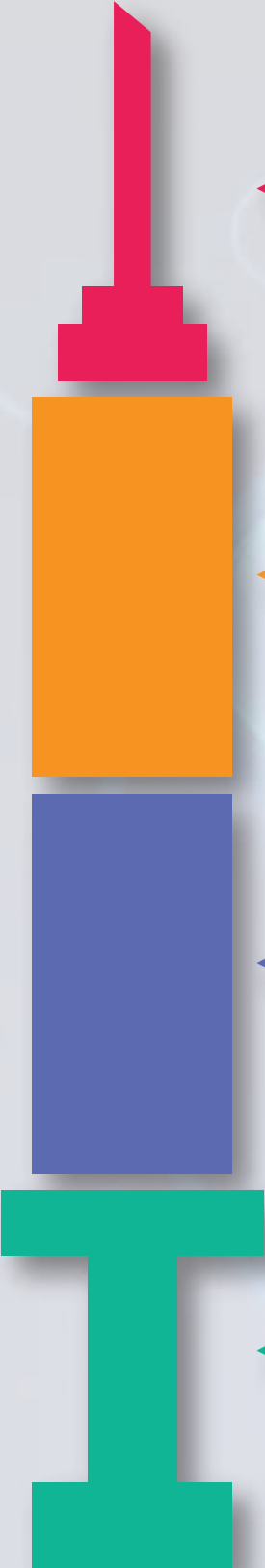


2024

Expected growth in biosimilar approvals as patents expire



PATENTABLE COMPONENTS



Production Process:

- Novel cell lines for biologic production
- Advanced purification methods
- Innovative bioreactor designs

Formulation:

- Stabilizers that enhance shelf-life without altering efficacy
- Excipients that improve bioavailability

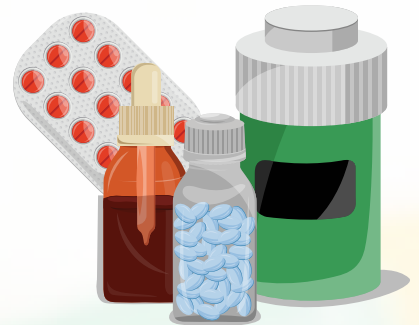
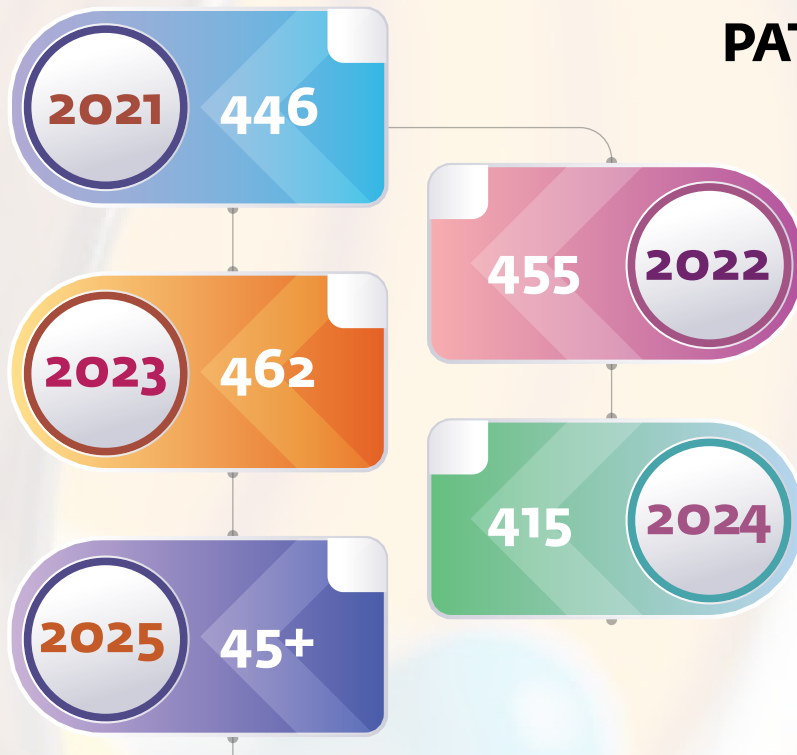
Delivery Systems:

- Prefilled syringes with enhanced stability
- Auto-injectors tailored for biosimilars

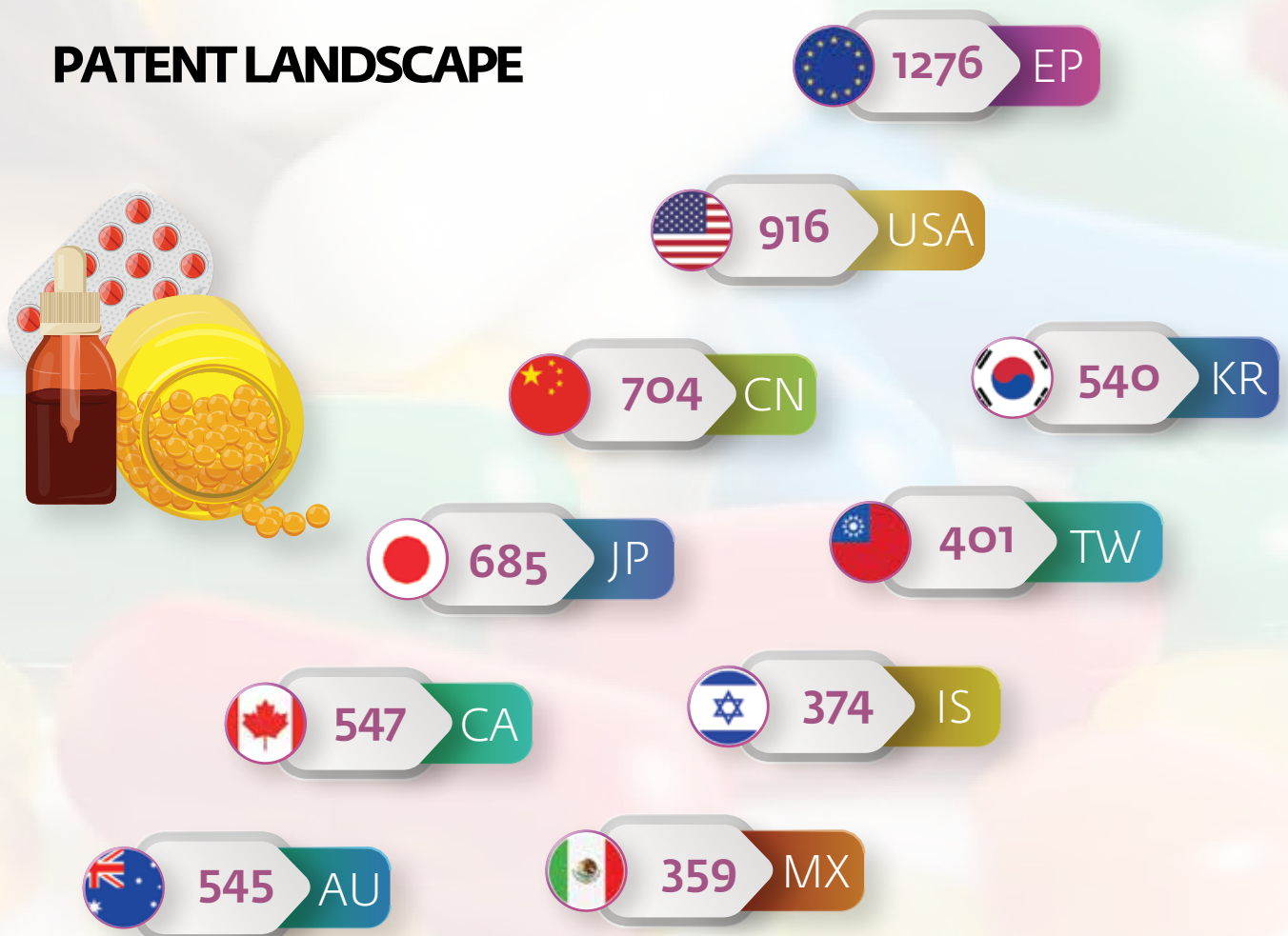
Analytical Methods:

- Techniques for assessing bio-similarity
- Methods for detecting immunogenicity

PATENT STATISTICS



PATENT LANDSCAPE



Database: Questel Orbit
Data Range: 01/01/2020 - 31/07/2025

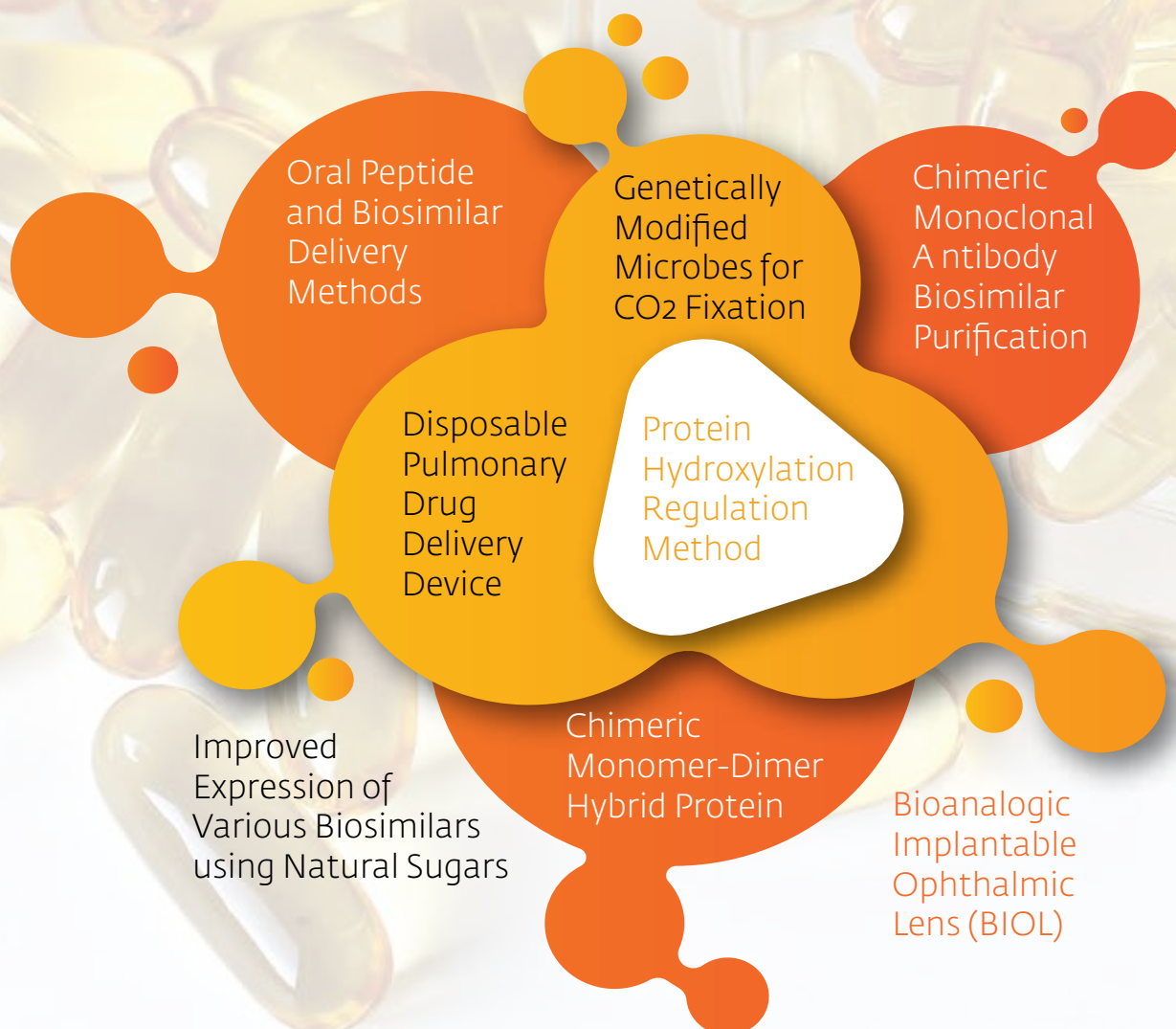
NOTABLE INNOVATIONS

Patent Application	Priority date	Title	Assignee
WO2024201501	24.03.2023	A process to produce a pharmaceutical composition	Dr. Reddy's Laboratories Limited
IN201717030146	14.10.2016	Compositions and methods of using a soluble TNF alpha receptor modified for increased half life	Merck Sharp & Dohme Corp.; Eisai R&D Management Co., Ltd.
US20170189527	23.05.2014	Adalimumab formulations	Fresenius Kabi Deutschland GmbH
US20080213280	20.03.2008	Therapy of autoimmune disease in a patient with an inadequate response to a TNF- α inhibitor	Genentech Inc
US20070258984	14.06.2007	Treatment with anti-VEGF antibodies	Genentech Inc
US20090176692	11.07.2006	Amidated insulin glargine	Sanofi-Aventis Deutschland GmbH
US20040194155	01.10.2002	HBV mutations associated with reduced susceptibility to adefovir	Gilead Sciences
US20080038261	11.08.1998	Combination therapies for b-cell lymphomas comprising administration of anti-cd20 antibody	Biogen Inc
EPO868194	20.12.1995	Combination of G-CSF with a chemotherapeutic agent for stem cell mobilization	Roche Diagnostics GmbH
EPO409870	15.04.1988	Human growth hormone formulation	Genentech Inc.

TOP APPLICANTS



WHITESPACES



If you would like to learn more about any of these areas or have specific questions, we're here to provide further information and insights. Our team is dedicated to driving progress and staying at the forefront of Biosimilars.

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