THE RISE OF BIOLOGICS: EMERGING TRENDS AND OPPORTUNITIES

An increasingly complex competitive landscape



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Introduction

In this era of contemporary medicine, we are seeing an increasingly varied landscape of biological drugs designed to target everything from cancer to infectious diseases. From monoclonal antibodies and therapeutic proteins to recombinant DNA and RNA interference (RNAi), biologics are the most promising category of new drugs in the 21st century.[1]

In this white paper, we will look at how biologics-focused drug discovery is continuing to grow, reflecting on global trends over the past 35 years and the contributing factors leading to this growth. We will also look at the current challenges faced in developing biologics and the impact on emerging markets.

Biologics — on an upward trajectory

Biologics research and production have grown rapidly in the past few decades, with no signs of slowing down. Sales of biologics are predicted to significantly overtake innovative small molecules by $120 billion by 2027, accounting for 55% of all innovative drug sales.[2]

Valued at approximately $343 billion in 2021, the global biologics market is expected to reach $569.7 billion by 2027 — a growth of 9.2%.[3] This biologics boom is undoubtedly driven by extensive research and development activity. CAS data demonstrates an ever-increasing footprint of biologics, both in published journal articles and patent applications (Figure 1).

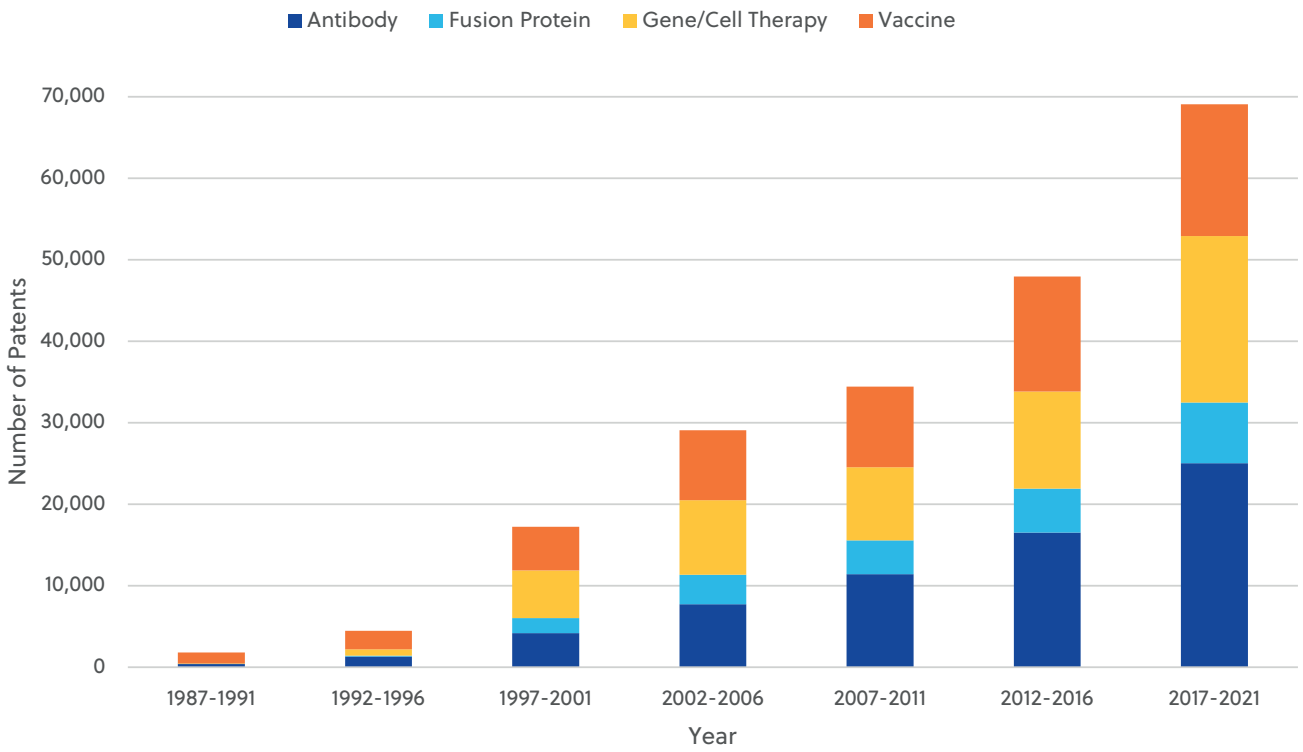


Figure 1. Global patent trend in biologics from 1987 to 2021 (CAS Content Collection™)

Although monoclonal antibodies are expected to dominate the landscape, nearly all subtypes of biologics are predicted to grow significantly in the next five years. The market for gene therapies and gene-modified cell therapies is set to grow by 39.6% between 2022 and 2027.[4] This expansion will be driven by sales of currently unapproved yet promising pipeline therapies such as RP-A501, a Phase I gene therapy indicated for glycogen storage disorders.[5]

The therapeutic potential of RNA-based therapies, which are used to modify gene expression or introduce new genes to target cells, is becoming a very competitive space. The recent enormous success of the messenger RNA (mRNA) COVID-19 vaccines has positively contributed to placing RNA-based therapeutic strategies on the medical center stage.

Currently, there are more than a dozen U.S. Food & Drug Administration (FDA) approved RNA-based therapies within five major categories of RNA therapeutics: [6]

- Small interfering RNAs (siRNAs), which are double-stranded and prevent the translation of their target protein by degrading mRNA after transcription
- RNA-based aptamers, which are short single-stranded RNA-based oligonucleotide ligands that assume various shapes and bind with high affinity to their target proteins to promote or inhibit their physiological effect
- RNA-based antisense oligonucleotides (ASOs), which are short single-stranded RNAs capable of silencing or promoting gene expression
- Messenger RNAs (mRNAs), which carry the genetic material that encodes for proteins

The growing acceptance of RNA as a drug and recent major discoveries of different RNA types significantly widened the scope and potential of RNA therapeutics.

Despite mRNA, RNA enzymes (ribozymes), and ribosomal RNA (rRNA) dominating research for decades, RNA-related publications and patents recently observed a shift toward the use of RNA in medicine, reporting a growing interest in transfer RNA (tRNA), short hairpin RNA (shRNA), long non-coding RNA (lncRNA), circular RNA (circRNA), piwi-interacting RNA (piRNA), exosome RNA, and clustered regularly interspaced short palindromic repeats (CRISPR).[7–11]

For example, companies such as Laronde[12] and ORNA™ Therapeutics[13] found that circRNAs degrade at a slower rate and are more stable than mRNA, which could make mRNA therapies safer and longer-lasting. Given the diversity of RNA molecules, it is not surprising that interest in RNA-based medicine will continue to increase.

In addition to RNA-based therapies, antibody-drug conjugates and antibody-ASO conjugates are also emerging areas within biologics.

Companies like Dyne Therapeutics[14] have initiated patient clinical trials for two of their lead antibody-ASO conjugate candidates, DYNE-101 and DYNE-251,[15] to enable targeted muscle tissue delivery for the treatment of myotonic dystrophy type I and Duchenne muscular dystrophy via exon skipping in the nucleus.

Another emerging area involves chimeric antigen receptors (CARs) for use in CAR T-cell therapy. CARs are engineered chimeric receptor proteins that provide antigen-binding and T-cell activating functions for cancer immunotherapy. The global market for CAR T-cell therapy is predicted to grow to $13.5 billion by 2028.[16]

Factors driving the growth of biologics

Biologics have revolutionized healthcare since the 1970s with a significant impact on the management of immune-mediated diseases such as inflammatory bowel diseases[17] and rheumatoid arthritis.[18] Biologic therapies provide symptomatic relief and improve quality of life in patients who have failed to respond to conventional disease-modifying agents.

The success of biologics is down to several key factors.

Biomanufacturing and safety testing

While the production and purification of biologics are more complex than traditional pharmaceutical drugs, significant advances are constantly being made to optimize the process. Because it relies on specially engineered living organisms, biologics production presents higher risks of batch-to-batch variations, microbiological contamination, and limited potential for high-scaling. However, growing interest in viral testing and refinements in clearance methods highly contribute to improving contamination-free production, with the global biologics safety testing market expected to almost double by 2027.[19]

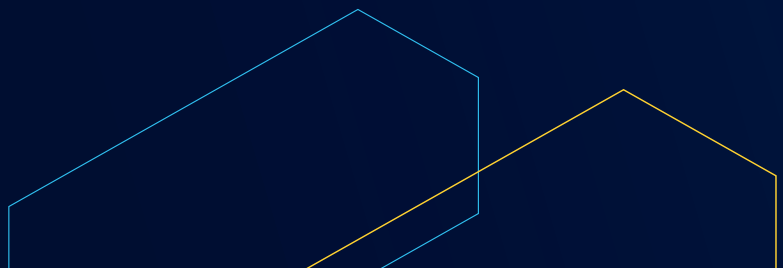
Biologics manufacturing is evolving rapidly. Emerging Bioprocessing 4.0 solutions, including machine learning and integrated automation and digitization, open the door to biology industrialization and fast-track the development of new biologics processes in the clinical setting.[20] Benefiting from major technological advancements, the ever-growing biologics market size is expected to be worth around $719.84 billion by 2030.[21]

Regulation updates

Biologics growth has also been facilitated by the clearance of major regulatory hurdles in recent years. In 2018, the FDA overhauled its regulations on general biologic standards for the first time since 1977.[22] This included an update of its outdated "duties of inspector" requirements for biological products,[22] allowing the FDA to adopt a more efficient risk-based approach to the inspection of biologics manufacturing facilities.

The FDA also removed an outdated rule (Section 610.20) requiring biological products to be tested against standard preparations from the FDA's Center for Biologics Evaluation and Research, allowing companies to obtain these from other sources or develop them internally.[23] Another rule (Section 610.21) that specified minimal potency limits to be met for certain antibodies and antigens was also removed.[23] Finally, regulations on the storage periods and storage conditions for biologics (Section 610.53) were also updated to include currently licensed whole blood and blood component products.[23] Collectively, these changes were designed to help cut the time-to-market and development costs for new drugs, and drive the market for biologics.[24]





Clinical applicability

A recent analysis performed by CAS reports a significant number of biologics-related documentations, covering at least 25 conditions including immune-mediated and infectious diseases. Data places oncology as the leading research field of interest for biological molecule application, accounting for about half of all assessed journal publications and patent applications.[25] This ever-growing interest for biologics shows researchers' increasing efforts in developing effective biologic treatments and pushing medicine boundaries to fill in the gap left by conventional chemical drugs. (Figure 2)

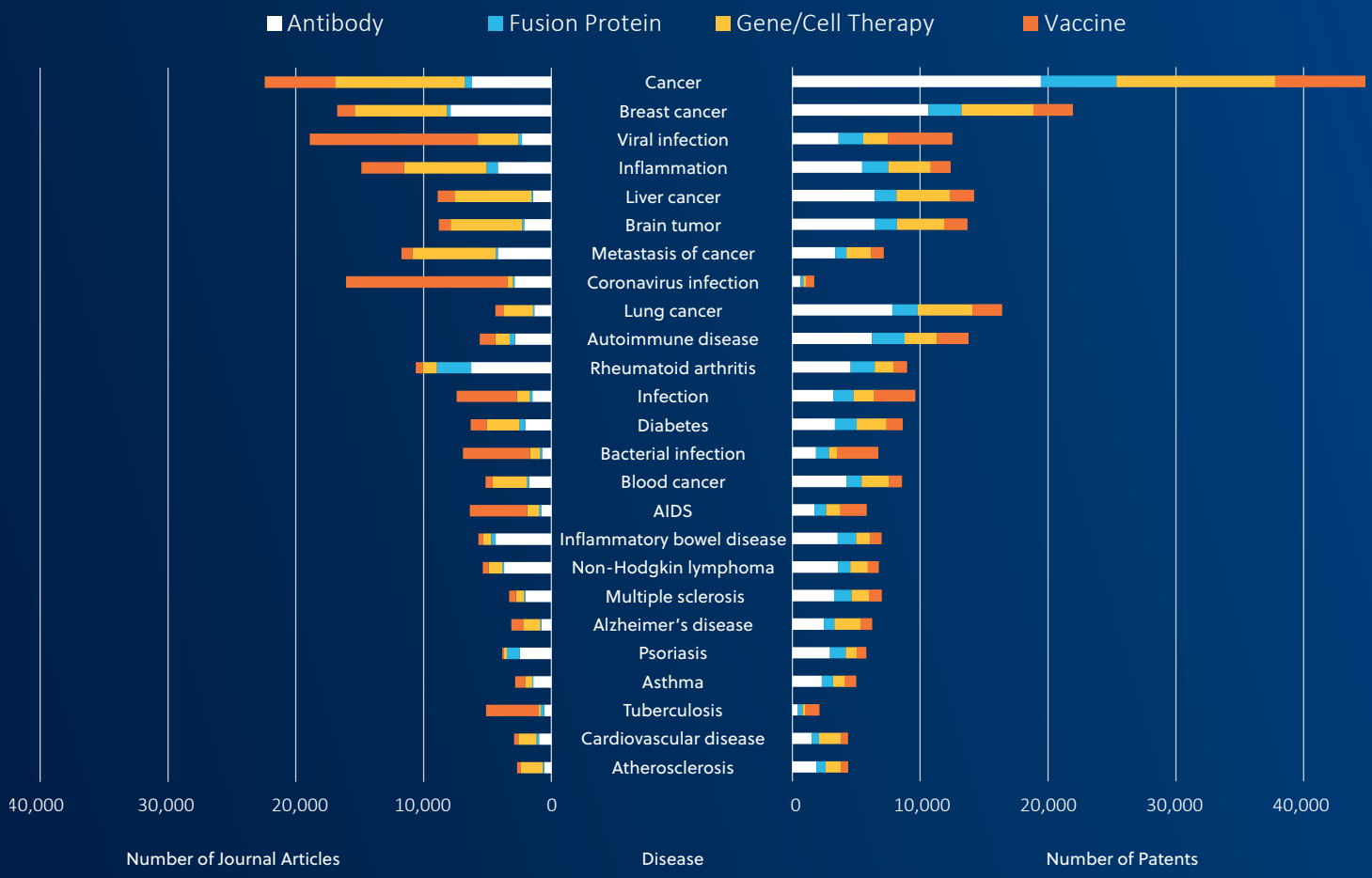


Figure 2. Biologics-related documentation distribution per disease

Financial support and accessibility

As our understanding of disease processes has evolved at the molecular level,[26] we have been able to create innovative biologics with entirely new mechanisms of action. The promise of these new therapies has led to increased investment in the development and implementation of biologics across the globe.[3] Although some discrepancies between countries remain, more investment helps companies boost their manufacturing capabilities, enabling the production of cheaper biologics.[27]

Insights on biologic innovation

Trends in patent filings and publications can tell us much about the current key players in biologic innovation: the United States, China, Japan, Germany, and the United Kingdom. CAS data from these five countries covering the period 1987–2021 shows that the United States saw the largest growth in biologic treatment patents and journal articles relating to biologics, closely followed by China — a key player that has displayed exponential growth in recent decades[31] (Figure 4).

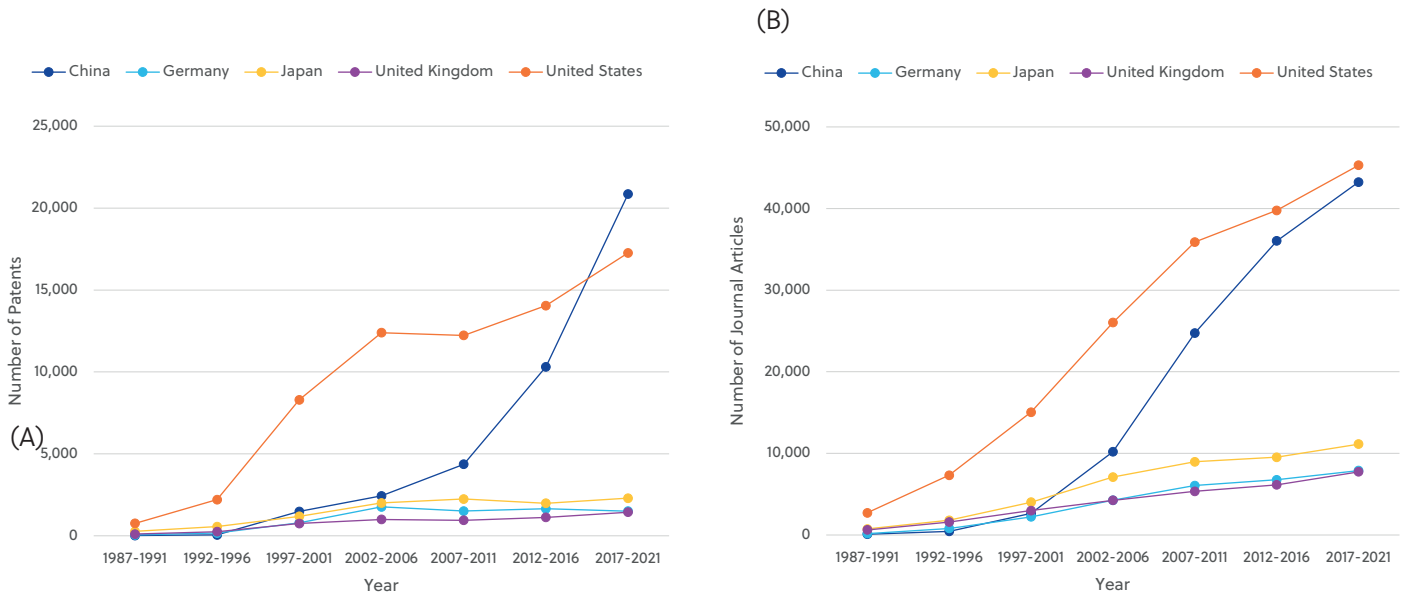


Figure 4. Country trends in (A) biologics treatment patent filings and (B) biologics journal articles from 1987 to 2021 (CAS Content Collection™)

An analysis of more than 600,000 biologics **journal articles** published between 1987 and 2021 shows that the gene/cell therapy class had the largest number of published **publications**, comprising 247,141 in total, followed by vaccines (214,998), antibodies (147,193), and fusion proteins (18,146).[31]

Public opinion and acceptability

An analysis of the CAS Content Collection revealed that over 500 patents for the treatment and/or prevention of SARS- and MERS-related diseases were filed between 2003 and 2020.[28] Most of these patents were related to vaccines for SARS and Middle East respiratory syndrome (MERS) (Figure 3). Recent COVID-19 pandemics and the undeniable success of mRNA COVID-19 vaccines have contributed significantly to the acceleration of this trend, bringing biologics potential to the attention of the general public. Despite initial reluctance toward mRNA vaccines, numbers from 2023 report that 69.5% of the world population had received at least one dose of COVID-19 vaccine — an encouraging percentage translating a shift in public opinion and growing acceptance of biological therapies.[29]

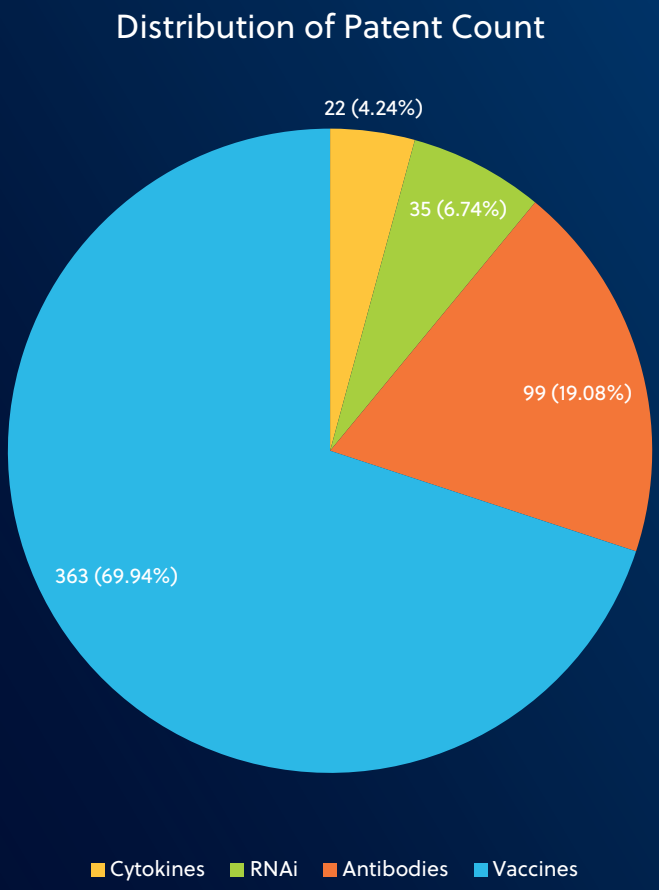


Figure 3. Distribution of patents related to SARS and MERS combined RNA (Liu C et al 2020)

Collectively, these factors have contributed to biologics overtaking the growth of small molecules. The growth of small molecules has declined in recent years[27] despite major drug launches in areas such as hepatitis and oncology. In fact, pharmaceutical companies that have predominantly been invested in small molecule research are now embracing the biologic wave. AstraZeneca has expanded its small molecule-driven respiratory portfolio to include the biologic benralizumab,[27] an interleukin-5 therapy indicated for eosinophilic asthma.[30]

Barriers to the growth of biologics

Despite the upward trajectory of biologics, several challenges remain. The longer it takes to bring a drug to market, the more expensive and less competitive a biologic will be. This is why increased efforts have been made in recent years to accelerate monoclonal antibody product development. As a result, the timeline from lead monoclonal antibody identification to Phase I investigational new drug application has nearly halved in the last decade.[32] This dramatic reduction is due to a combination of technical advances and increased acceptance of business risks, allowing for rapid clinical production capacity without compromising on product quality or patient safety. This acceleration of early-phase clinical development has led experts to ascertain whether the development time of a lead monoclonal antibody could be achieved in just two years.

Patenting issues

Though research and development may be speeding up, the field of biotechnology brings a unique set of patentability issues.[33] For instance, the issue of how to define and adequately address enablement, as required by law, is one of the most pressing patent issues facing innovators. Questions around how to describe a biotechnology innovation so that a person skilled in the art can replicate it without undue experimentation, and how to define whether claims are too broadly written in covering genus, lie at the heart of judicial review.

Furthermore, determining the industrial applicability of an innovation can present challenges when its future application is yet to be determined. Finally, issues that result from the fact that biological material can reproduce itself carries a range of implications that need to be addressed before exclusivity can be granted. This complexity often leads to patent disputes that are challenging to resolve. A patent dispute over the revolutionary CRISPR-Cas9 gene-editing tool that began in 2016 is ongoing to this day, as the intellectual property around the technology is growing more complex.[34]

Patents also have a limited shelf life. Patent expiration and loss of exclusivity is a challenge facing manufacturers of numerous biological medicines, leading to increased development and commercialization of biosimilars.

Manufacturing complexities

Biologics offer distinct advantages that small molecule drugs do not. However, they are far more complex to develop and manufacture.[35] Compared with small molecules, biologics manufacturing requires more planning, investment, and multi-disciplinary personnel. Biologics are generally less robust than small molecules; they are both light and temperature-sensitive and more prone to shearing and degradation. Therefore, manufacturing biologics requires highly engineered specialized equipment to minimize challenges as the therapy moves from discovery to commercialization. This is an important consideration for companies looking to invest in biologics production as part of their strategic mission.

The impact of biosimilars

Finally, it is also important to consider the impact of biosimilars on the biologics sector. As biosimilars are similar to already authorized biologics, developing these agents saves time and resources by avoiding unnecessary duplication of clinical trials.[36] Though the EU has the most mature biologics market,[37] the U.S. market is also growing rapidly, with 39 FDA-approved biosimilar products to date.[38]

Biosimilars have had a positive impact on patients, enabling wider access to better-value biologics.[27] However, increasingly competitive pricing is expected to dampen the growth of biologics.[38] This has already been the case for Johnson & Johnson's biologic Remicade, which has faced biosimilar competition since 2016, while sales revenue for Pfizer's biosimilar Inflectra grew from $192 million in 2016 to $642 million in 2018.[39]

To help offset the risks of biosimilar competition, many pharmaceutical companies have begun to invest in their own products. For instance, Amgen[40] has developed biosimilars for infliximab, rituximab, and bevacizumab, amongst others — helping to soften the blow from the upcoming patent expiry of blockbuster Xgeva (denosumab) in 2025.[41] Pharmaceutical companies are increasingly taking advantage of the biosimilar opportunity to maximize their profits.[42] In 2021, Novartis advertised 406 new biosimilars jobs and mentioned biosimilars in company filings 119 times.[43] With such fierce competition, innovation will be key to lessen the impact of biosimilar revenue erosion. Roche has created a subcutaneous formulation of its breast cancer drug Herceptin (trastuzumab), which has taken 28% of franchise sales for treatment of human epidermal growth factor receptor 2 (HER2)-positive disease.[27] This new formulation of Herceptin reduces treatment time from 30-90 minutes to five minutes, proving that follow-on innovation can improve patient outcomes while netting profit for companies.

Biologics in emerging markets

In developing economies where resources are limited, biologic treatment rates are still low. In China, fewer than 10% of patients with colorectal cancer are treated with biologics, compared with 55% in the United States.[44] Similarly, 20–25% of newly diagnosed Chinese patients with breast cancer are treated with biologics, compared with more than 70% in the United States. Other therapeutic areas show similarly wide gaps, meaning that a disproportionate number of patients do not have access to innovative medicines that could optimize treatment outcomes. Other developing countries are also impacted by low biologic treatment rates.[44] In Brazil and Mexico, up to 40% of patients with tumor types eligible for treatment with biologics do not receive this therapy. This presents attractive opportunities for biosimilars.

Multinational pharmaceutical companies are setting out to harness opportunities in emerging markets, helping to bring affordable biosimilar treatments to the patients who need them most. Development pathways are currently being established in nations such as China, India, Russia, Brazil, Mexico, Indonesia, Vietnam, Turkey, and Egypt.[44] Each market brings its own set of regulatory, payer, and procurement challenges, so companies will need to be strategic in their approach. To succeed, companies will need to adapt their business models to the markets they target and be able to respond rapidly to local needs.

The future for biologics

Biologics represent a growing share of the market, with research and development of biologic agents likely to expand as technologies mature. The trend of intensified research activity catalyzed by the COVID-19 pandemic is set to continue, yielding new products and innovations in biological technologies.

Once seen as an expensive alternative to small molecules, biologics are becoming an increasingly attractive prospect for pharmaceutical companies. As our understanding of disease processes at a molecular level has expanded, so too has the promise of new biologic agents to address areas of unmet need. Biologics are becoming more cost-effective to produce, thanks to technological innovations yielding more streamlined manufacturing processes. Though they are likely to remain more costly than small molecules, biologics are set to become more accessible due to larger patient populations and high-volume production.

The question to ask is whether the promise of biologics will be fulfilled. The looming threat of biosimilars will present new challenges for pharmaceutical companies due to increasingly competitive pricing. Companies will need to act strategically to ensure they achieve a good return on investment in this shifting market. In this increasingly competitive landscape, many companies are turning their attention to emerging markets, such as China and Brazil.

At CAS, we offer a range of resources to help you leverage the potential of biologics[1] and the RNA therapeutics revolution.[45] With a full continuum of intellectual property support, we deliver the quality insights you need to make confident business decisions.

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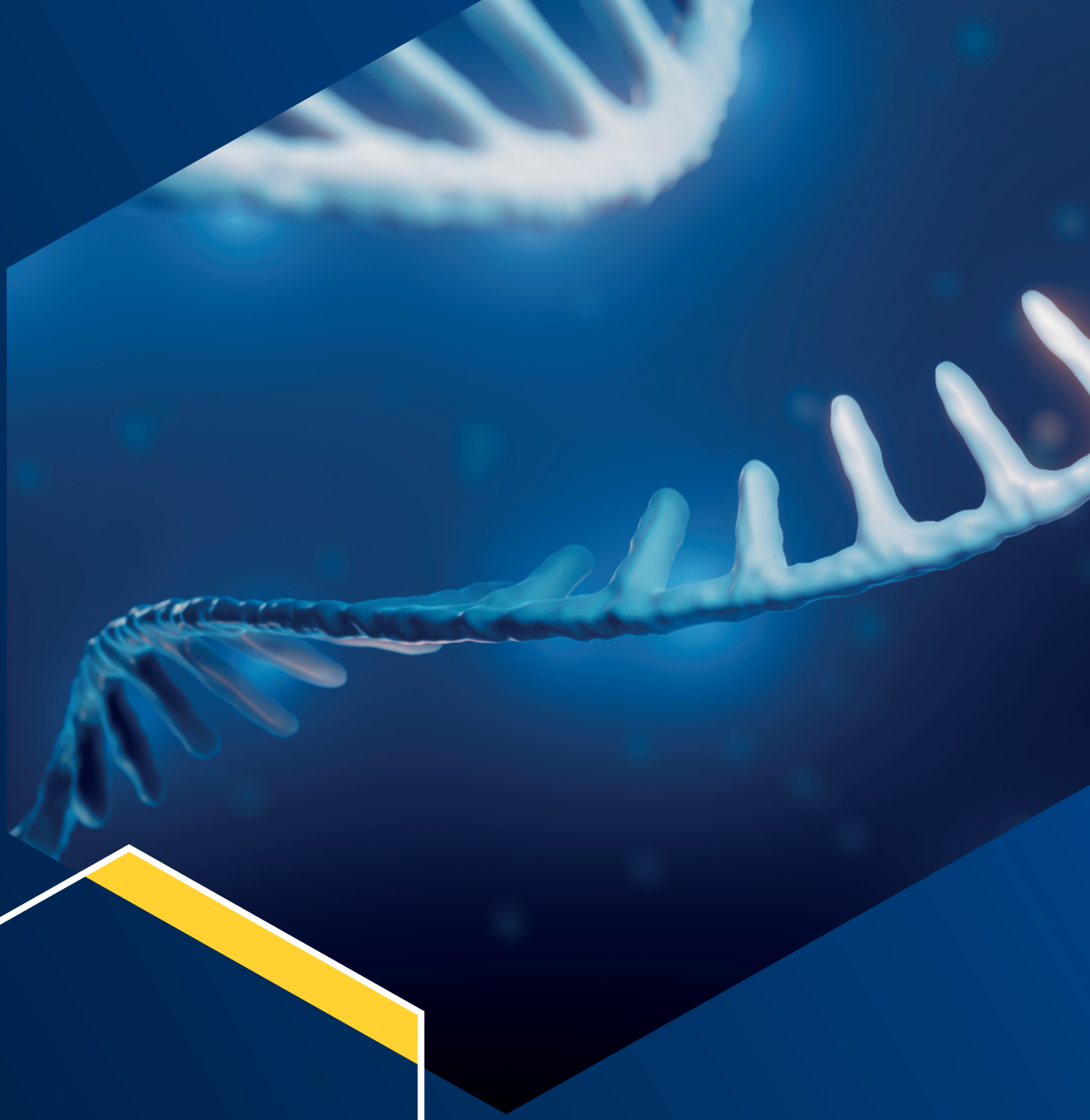
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