

The business of biologics: How strategic IP intelligence protects innovation and unlocks opportunity

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Ready to strengthen your biologics IP strategy?

Executive summary

Biologics are reshaping the future of medicine, and the competition to capture market share is intensifying. Drawing on real-world insights and expert commentary, we explore how early, data-driven IP planning protects pipeline value, enables informed investment decisions, and strengthens positioning for licensing, partnerships, and M&A.

You will discover:

- How IP search and monitoring can identify competitive threats before they impact your business.
- Why real-time visibility into patent landscapes is essential for mitigating litigation risk and preserving deal value.
- The importance of sector-specific IP strategies—from mRNA and gene therapies to AI-discovered biologics.
- How executive teams can use IP intelligence to prioritize high-return R&D and avoid costly missteps.



Biologics innovation: Opportunity and competition

Driven by scientific breakthroughs and the rise of personalized medicine, biologics now represent a growing share of global pharmaceutical pipelines. By 2027, biologics sales are projected to surpass small-molecule drug sales by more than \$120 billion, accounting for over half of innovative drug revenues.¹

This growth is powered by expanding pipelines in oncology, rare diseases, and metabolic disorders, along with increasing adoption of biosimilars and next-generation therapies like mRNA biologics.



However, biologics are significantly more complex—and costly—to develop than traditional drugs. Their production demands specialized manufacturing, rigorous safety evaluation, and evolving regulatory pathways. Moreover, biosimilar competition and looming patent cliffs threaten to erode market share quickly.

In this environment, IP intelligence is critical. Strategic patent search and monitoring enable organizations to:

- Track competitive developments.
- Anticipate litigation and enforcement risks.
- Identify licensing or white space opportunities.
- Align innovation with commercial goals.

This white paper explores how forward-thinking biopharma companies are refining their IP strategies to stay ahead of market shifts, mitigate risks, and capture long-term value.

What's driving biologics innovation?

The biologics market is projected to exceed \$1 trillion globally by 2034.² Several interconnected forces are fueling this extraordinary growth:

Global demographic shift	Rise of personalized medicine	Supportive regulatory landscape
By 2030, 1 in 6 people will be aged 60 or older, rising to nearly 1 in 5 by 2035—representing over 2.1 billion individuals globally. ³ This aging population will drive unprecedented demand for biologics that target chronic and age-related diseases such as diabetes, cardiovascular diseases, cancer, and dementia.	Advances in genomics, biomarker discovery, and data science are fueling significant growth in personalized treatment approaches. Personalized therapies represent over 35% of FDA-approved drugs in recent years, with oncology and rare genetic diseases dominating biopharma development pipelines. ⁴	Fast-track designations, adaptive pathways, and growing investments in biologics are creating faster routes to commercialization. In 2023, 65% of novel biologics approved by the FDA benefited from expedited programs, accelerating revenue opportunities in high-need disease areas. ⁵



These factors impact large populations and involve complex disease mechanisms that biologics are suited to address. Advances in monoclonal antibodies, antibody-drug conjugates, gene therapies, and mRNA-based platforms are transforming “undruggable” targets into viable therapeutic opportunities.

Regulators are also evolving their frameworks to support this pace of innovation. In the United States, the FDA’s Fast Track and Breakthrough Therapy programs offer expedited review for biologics that show early potential in treating serious conditions.⁶ The European Medicines Agency has also implemented adaptive pathways, which allow conditional approvals in select cases, especially when large-scale trials are impractical.⁷

These trends suggest significant commercial opportunity and a crowded, high-stakes IP arena. As biologics pipelines expand, success will depend on scientific leadership, strategically navigating the IP landscape, protecting market positions, and outpacing competitors.

Patent trends in biologics: Protect your edge in a high-stakes market

Innovation in biologics is mirrored by an uptick in global patent activity. In 2024, the FDA's Center for Drug Evaluation and Research (CDER) approved 21 biologic license applications (BLAs), maintaining momentum from 2023,⁸ with key therapeutic launches across oncology, autoimmune diseases, and rare genetic conditions.

However, many top-performing biologics are nearing or have passed their patent expirations. Johnson & Johnson's Stelara, which earned \$6.7 billion in U.S. sales in 2024, now faces multiple biosimilar challengers. Other products such as Regeneron's Eylea, Amgen's Prolia/Xgeva, and Novartis's Entresto are also approaching major loss of exclusivity events.¹⁰

In response, many companies seek to extend exclusivity through secondary patents on new formulations, delivery mechanisms, indications, and dosing regimens. Such strategies can be effective but are vulnerable to biosimilar challenges and regulatory scrutiny.

To protect assets and avoid costly disruption, organizations must:

- Secure strong primary and secondary patents early.
- Conduct regular patent landscape reviews and FTO assessments.
- Monitor competitor filings, litigation trends, and enforcement risks.

"As the volume and complexity of scientific data grows exponentially, it becomes more difficult to get a clear view into a particular space of interest. We see this challenge across many domains, but perhaps most acutely when it comes to biotech innovations."

Cathy Van der Herten
Director of Product Management, CAS

Your team needs solutions that deliver clear, early visibility into the global patent landscape, especially across complex biological sequences, structures, and emerging therapeutic areas. Precision IP search and monitoring tools, like those offered by CAS, enable early threat detection and more strategic, confident decision-making.

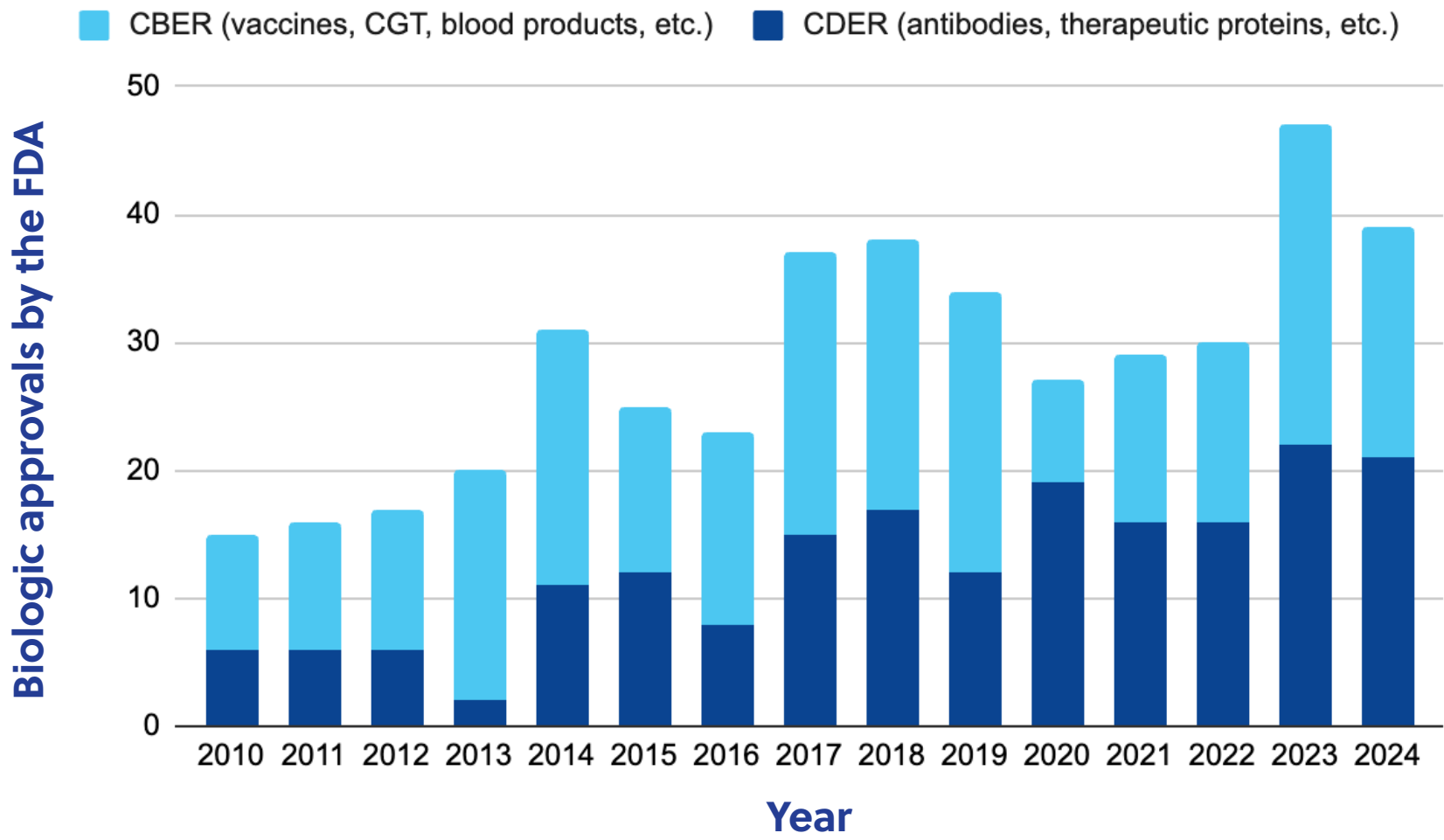


Figure 1: BLA approvals by the FDA's Center for Biologics Evaluation and Research (CBER) or Center for Drug Evaluation and Research (CDER) from 2010–2024.^{8,9}

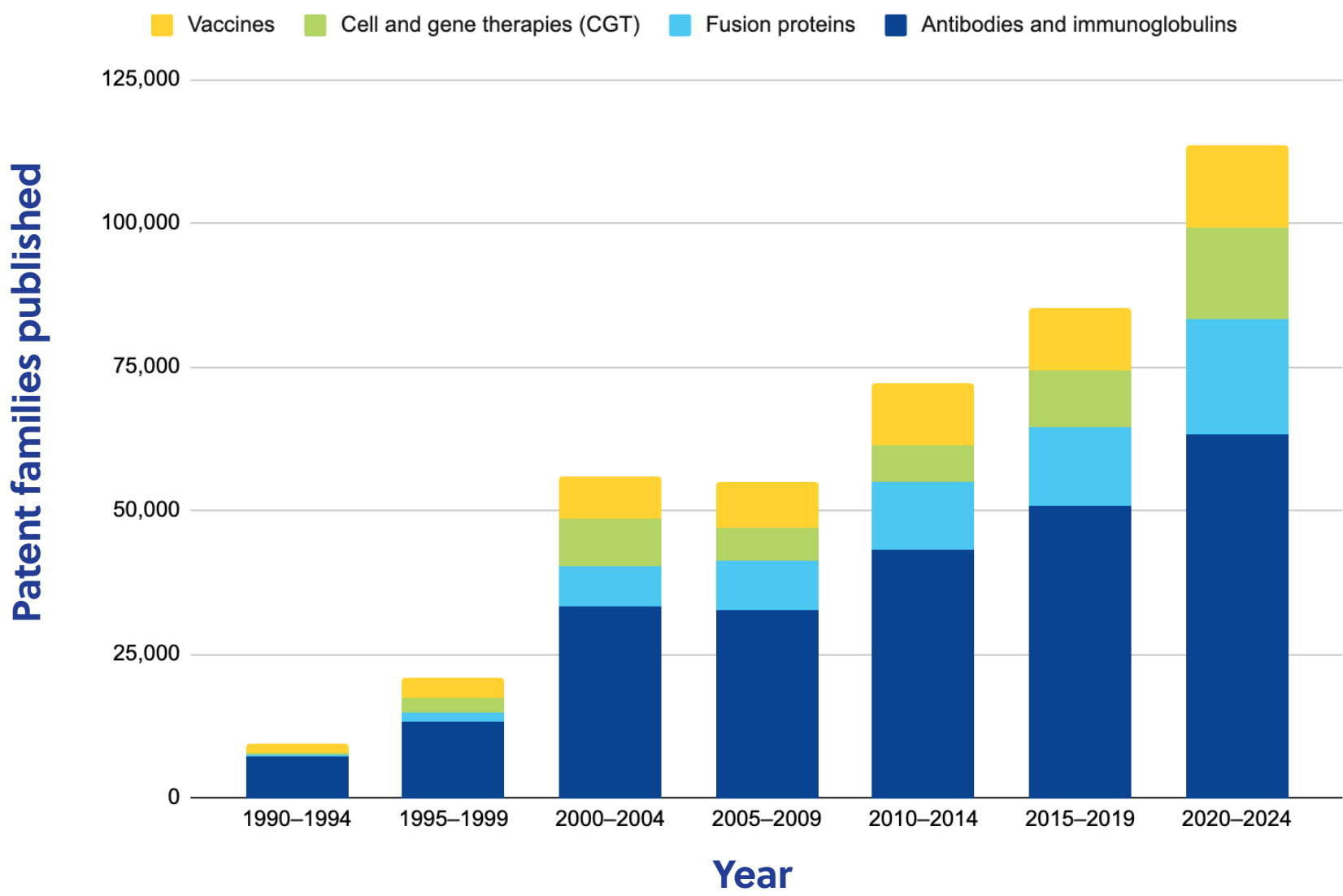


Figure 2: Global patent trend across biologics categories from 1990–2024 (CAS Content Collection™).



Use IP intelligence to drive smarter business decisions

In a complex biologics market, success depends as much on IP strategy as scientific innovation.

IP intelligence informs critical decisions across the development lifecycle:

- Evaluating freedom to operate (FTO)
- Identifying patentability and filing opportunities
- Monitoring emerging risks through ongoing surveillance

Note that any patent search provides only a snapshot in time. The landscape evolves daily, with new filings, litigation updates, and regulatory shifts. Continuous monitoring is essential to maintain a competitive advantage.

“You can’t think ‘Oh I’ve done a search, I checked that box, I can walk away.’ As a project develops, what you needed last year isn’t what you need right now, and what you need next year isn’t what you need right now. It’s very iterative.”

Anne Marie Clark, Ph.D.
Senior Scientist, CAS IP ServicesSM

With biologics, this monitoring must account for changes in therapeutic categories, delivery mechanisms, and manufacturing innovations. A pending patent application could shift the competitive landscape or narrow a company’s freedom to operate. Early visibility is key.

As in any scientific field, biologics patent documents can be dense and misleading, and key information may be hidden in non-patent literature, like conference proceedings or regulatory filings. Assessing real-world impact requires experience and access to integrated data sources.

Successful IP search and monitoring strategies rely on comprehensive, high-quality data from patent and non-patent sources. However, this information is often difficult to find. Trusted partners like CAS help remove this barrier by providing streamlined access to curated, validated information, including biomolecule sequences and complex bioactivity information that standard search tools frequently miss.

Tips for building comprehensive IP intelligence strategies

- Collaborate early by integrating R&D, legal, and commercial teams.
- Define clear search parameters and prioritize quality search sources.
- Establish continuous monitoring workflows.
- Use sequence, structure, and concept-based tools for multidimensional insights.
- Partner with subject-matter experts for complex or niche tasks.

An effective biologics IP strategy supports confident decision-making, drives faster innovation cycles, and builds greater competitive resilience.

Harness sector-specific IP strategy for trending biologics

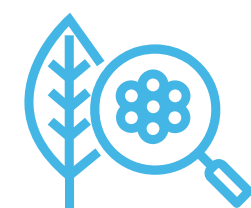
Biologics span many therapeutic areas and approaches, each with unique IP challenges. Tailoring IP strategy to the scientific, legal, and commercial dimensions of each biologic class is critical to mitigating risks and maximizing the value of your R&D investment.



Cell and gene therapies

Cell and gene therapies are at the forefront of personalized medicine, with 43 approved gene therapies¹¹ and many more in development.¹² Such therapies involve high degrees of scientific complexity, and IP protection usually focuses on engineered sequences, gene-editing tools, viral vectors, and cell modification techniques.

Recently, platforms such as CRISPR-Cas9 have dominated the landscape, and FTO assessments are critical to avoid infringement in a space that is already filled with overlapping claims. Additionally, protecting methods for ex vivo cell manipulation, expansion, and reinfusion provide avenues for extending exclusivity.



Biosimilars

The biosimilar market continues to expand as originator biologics lose exclusivity. Companies entering this space face complex patent thickets—networks of overlapping patents that may cover formulation, dosing, manufacturing methods, and delivery devices.

For companies trying to navigate this environment, strategic litigation planning and careful prior art analysis are needed. It's also important to understand the difference between biosimilars and interchangeable biosimilars. The latter meet additional requirements that allow the FDA to approve their use as a substitute for the original product without consulting the prescriber.¹³ Interchangeability status can influence IP protection and commercial strategy.



Vaccines and delivery technologies

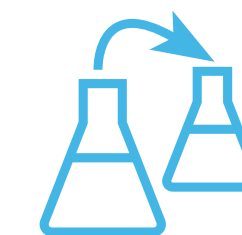
Thrust into the spotlight during the COVID-19 pandemic, the success of mRNA vaccines has highlighted the importance of delivery platforms. For instance, lipid nanoparticle (LNP) technology is a highly contested and competitive space. IP strategies in this field focus on composition protection, encapsulation techniques, stability profiles, and manufacturing protocols.

In parallel, personalized cancer vaccines and other next-generation immunizations require protection that encompasses the biologic construct and its delivery mechanism, with patents spanning mRNA sequences, adjuvants, and combination therapies.



AI-enabled biologics

Artificial intelligence is now being used to accelerate biologics discovery, from protein folding predictions to identifying novel targets. While patenting AI algorithms can be difficult, companies can protect downstream innovations, such as new biologics identified or optimized through AI processes. The integration of AI with traditional wet-lab validation can help meet the 'novelty' and 'non-obviousness' standards required by patent offices.

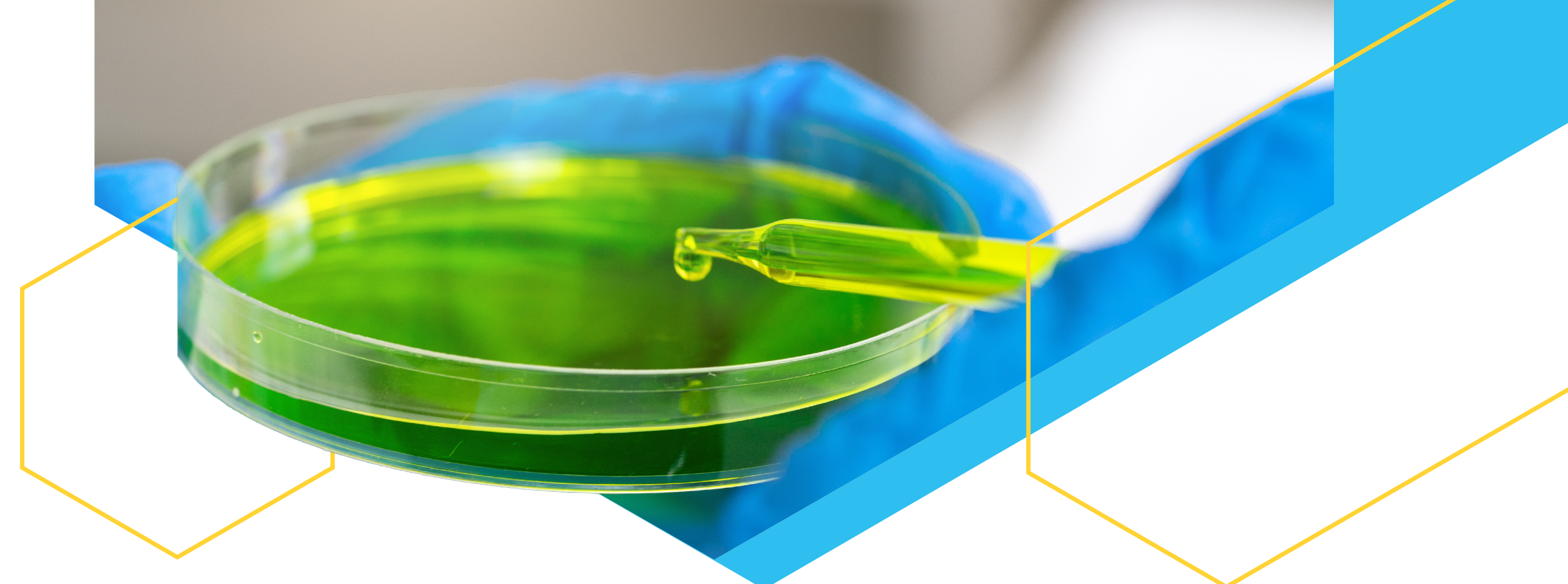
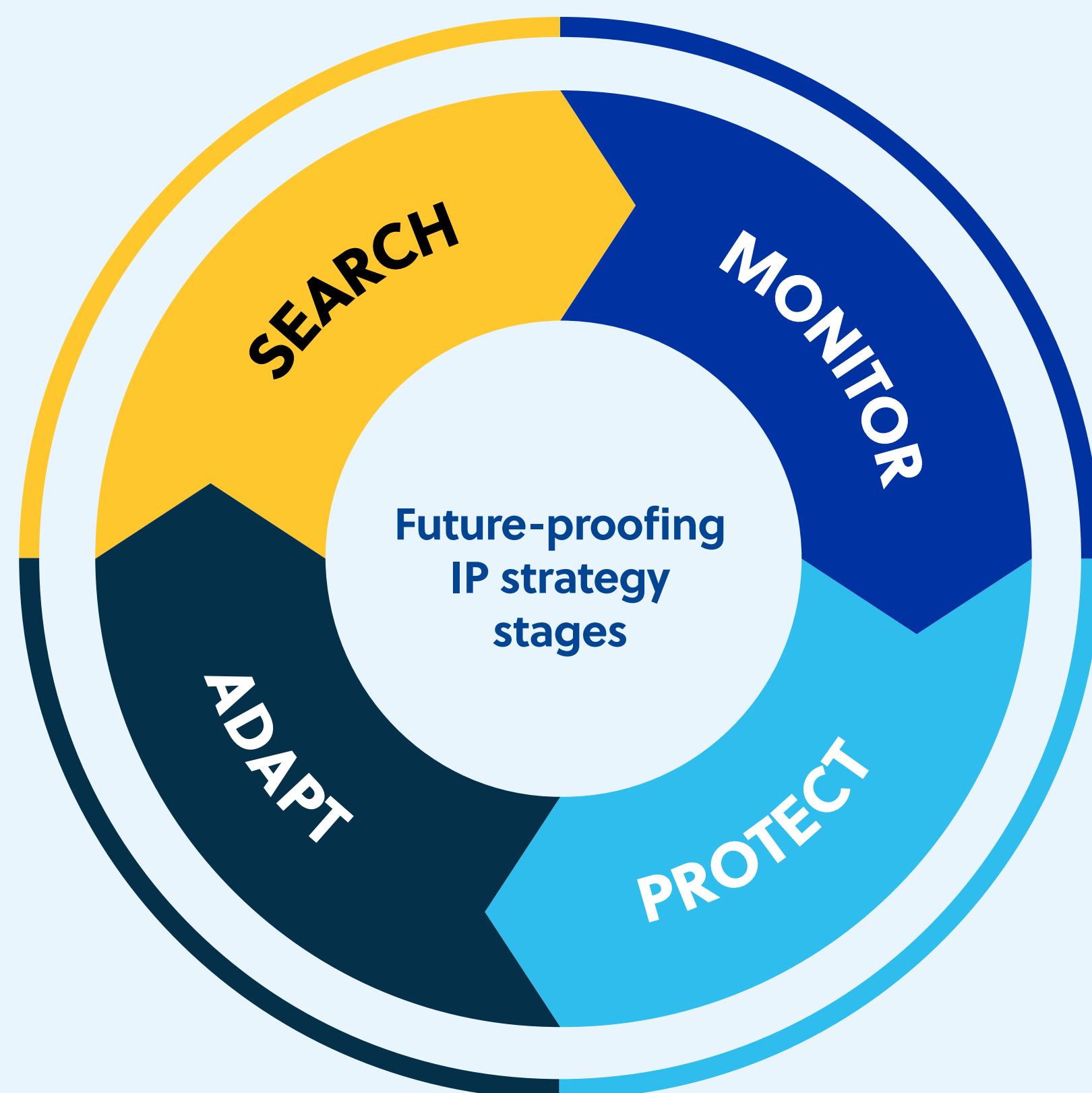


Manufacturing innovations

Across all biologics categories, production-related IP remains a valuable but sometimes underutilized asset. Patents covering purification steps, culture media formulations, or stability-enhancing processes can extend exclusivity beyond composition claims. In cell therapy development, proprietary bioreactors, closed-system workflows, and quality control assays are being captured in IP portfolios more often.

Strategies for future-proofing your IP

As biologics innovation continues to evolve, IP intelligence must become more data-driven and dynamic. Forward-thinking companies are adopting comprehensive IP search and monitoring tools and strategies to maximize market exclusivity, reduce risk, and uncover untapped opportunities.



Prioritize long-term monitoring programs

Patent searches capture a moment in time, but the landscape is dynamic. A new application filed tomorrow could impact your freedom to operate. Implementing a continuous patent monitoring process ensures you stay informed about relevant application changes, litigation activity, or shifts in competitor strategies.

By setting up customized alerts and watchlists, teams can track updates in real time and act quickly on competitive threats or partnership opportunities. CAS IP Finder, powered by STN™, offers monitoring solutions that deliver timely insights aligned with your R&D and commercial focus areas.

Search smarter with structure and sequence precision

Traditional keyword searches fall short when it comes to biologics. Even experts accustomed to small-molecule IP practice can face challenges due to the large molecular sizes and complexity inherent to biologics. Inconsistent terminology, biological variability, and post-translational modifications layer on additional difficulties when searching for relevant prior art.

Robust IP tools must allow multifaceted searches, such as chemical structure, biological sequence, or functional analogs. This enables better navigation of crowded fields and helps reveal less obvious risks or opportunities.

CAS IP Finder™ supports advanced sequence searching and bioactivity data integration, streamlining complex queries across global databases for more complete results.



3 Extend protection with strategic layering

To extend exclusivity beyond initial patents, companies frequently use life cycle management tactics such as:

- Filing secondary patents on new indications or combinations.
- Protecting innovative formulations or dosage regimens.
- Claiming delivery methods or manufacturing improvements.

Each layer must be well-supported by data and strategically timed to regulatory and market milestones. Careful planning also prevents earlier disclosures from becoming prior art against future claims.

Find the whitespace others miss

Whitespace analysis helps uncover underexplored technical areas, enabling you to focus R&D where the competitive pressure is low but commercial opportunity is high. This approach is useful for discovering adjacent applications, new therapeutic indications, or alternative delivery methods.

Tools like AI-enabled patent analytics, available through CAS IP Finder, help reveal novel connections across disciplines and reveal strategic filing opportunities.

Align IP with regulatory trends

As global regulators adapt their approval pathways—especially for rare diseases, personalized medicine, and accelerated review programs—your IP strategy should evolve accordingly. Understanding how IP and regulatory timelines intersect allows better coordination of filing, launch, and exclusivity extensions. Being the first to anticipate a shift in regulatory review criteria can give your team a crucial advantage.

Power your strategy with integrated intelligence

Successful biologics IP strategies require cross-functional coordination and access to trustworthy, connected data. From genes to formulations to delivery systems, tracing innovation through its full biological and technical context is key.

CAS IP Finder offers seamless access to scientific literature, patent databases, regulatory documents, and biological sequences all in one place. This unified platform helps executive, R&D, and IP teams make aligned, confident decisions and stay competitive in a shifting environment.

“When I was in drug development, one of the first things everyone focused on was our own capabilities—what was our technological advantage. But we also needed to ask ourselves the question ‘what can we do that has sufficient white space and IP potential.’”

Gary Gustafson, Ph.D.
Senior Customer Success Specialist, CAS

Protect innovation and capture opportunity

Success in biologics depends on timely and accurate IP intelligence. Companies that invest in powerful tools and strategic foresight will be better positioned to innovate, protect their discoveries, and navigate change.

With expert support and an integrated view across scientific, patent, and regulatory domains, CAS IP Finder empowers your organization to turn complexity into a competitive advantage.





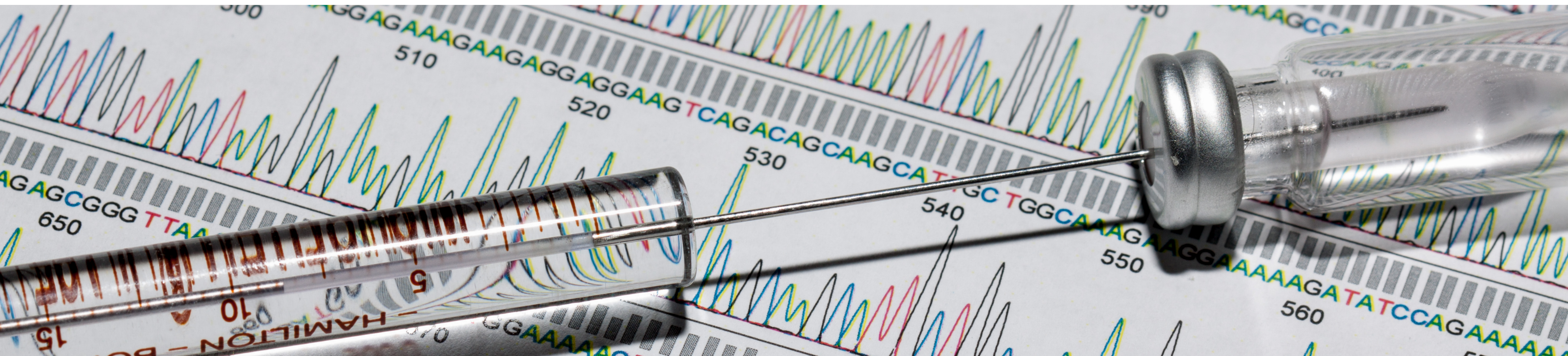
Ready to strengthen your biologics IP strategy?

See how CAS IP Finder helps organizations move faster, protect smarter, and innovate with confidence.

| [Learn more at cas.org](https://cas.org)

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CAS connects the world's scientific knowledge to accelerate breakthroughs that improve lives. We empower global innovators to efficiently navigate today's complex data landscape and make confident decisions in each phase of the innovation journey. As a specialist in scientific knowledge management, our team builds the largest authoritative collection of human-curated scientific data in the world and provides essential information solutions, services, and expertise. Scientists, patent professionals, and business leaders across industries rely on CAS to help them uncover opportunities, mitigate risks, and unlock shared knowledge so they can get from inspiration to innovation faster. CAS is a division of the American Chemical Society.

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