Center for American Principles

CAP ISSUE BRIEF:

Biopharmaceutical Patents

PRINCIPLE:

Health Through Innovation

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Biopharmaceutical innovation takes place within an ecosystem fueled by massive private-sector R&D investments that fund efforts to identify, develop, and test potential treatments against **unmet medical needs.** Up-front costs that would not otherwise be financed are secured by **patent rights** that accrue to breakthrough **inventions and discoveries**[i] realized at each stage of drug discovery, development, testing, and delivery. Where patients see only a maker of a pill or an injection, an innovative biopharmaceutical firm is in the business of holistically cultivating the **know-how** to address unmet medical needs or improve standards of care, along with the advanced manufacturing capabilities to reproduce the resulting therapies at scale.

Enormous Investments.

On average each new medicine approved by the U.S. Food and Drug Administration (FDA) takes **10 years** and costs U.S. firms more than **$2.5 billion** to develop. Only about 12% of potential drugs make it through the rigorous process to become FDA approved.

Key Takeaways

- The lifecycle of biopharmaceutical **innovation** encompasses research, development, testing, manufacturing, and delivery. At each stage, unique technical challenges must be overcome.
- A "patent" is a form of intellectual property providing legal title to work that results in a **novel** and **non-obvious** invention or discovery.
- Each pharmaceutical patent represents a new **solution** to a specific biomedical challenge.
- An innovative medicine typically combines solutions to a **range of challenges** each of which must be overcome in order to safely and effectively deliver a therapeutic benefit to a patient.
- Patent rights enable **investment and collaboration** throughout the innovation lifecycle by securing assets which can be shared via contractual licensing arrangements.
- In a process of **living innovation,** many therapeutically valuable discoveries come from patent-enabled investments that follow the initial launch of a new drug.

Issue Landscape

Empowered by America's respect for intellectual property rights, U.S. firms are the global leaders in biopharmaceutical innovation. Drug discovery is a long and expensive process. Only 12% of drugs entering clinical trials are ultimately approved by the FDA for patient use.[ii] Patent rights to work that results in new discoveries provide the innovator with an exclusive right to make and sell the resulting product, which enables the up-front investment of time and capital that must be risked to secure those advances. To ensure the spread of new knowledge, patents are time-limited and require the innovator to fully and publicly disclose their discovery. The 20-year patent term on a new molecule—the core of a new medicine—begins to run early in the process of drug discovery, years before a product ever reaches market, leaving innovators only a brief window to commercialize the resulting product and earn a return on large investments in research and development before competitors copy the product at far less expense. Patent rights to subsequent discoveries power a sustained lifecycle of investment and innovation that makes medicines increasingly safer, effective and useful through improvements to existing products.

A Policy Priority

First Line of Defense. Biopharmaceutical therapies are the first line of defense for Americans against disease and other health conditions: "In 2021, 64.8% of adults aged ≥18 years took prescription medication at any time during the past 12 months,"[iii] according to the Centers for Disease Control. While medicines play an outsized role in delivering health benefits to patients, "Total drug spending remains an important, but small part of total healthcare expenditure[iv]," says IQVIA. In sum, while biopharmaceutical products represent a small share of spending, they generate a large share of therapeutic benefit to U.S. patients and the health care system by keeping patients healthy and less likely to utilize other costly medical care, such as hospitalizations or physician services (collectively, 52% of all U.S. healthcare spending)[v].

Did You Know?

Medicines account for only about 14% of overall U.S. healthcare spending

Unmet Medical Need. The innovative biopharmaceutical industry, where patents play a critical role, is in the business of making new medicines that address unmet medical need. The National Center for Advancing Translational Sciences (NCATS), a department of the U.S. National Institutes of Health, defines an unmet medical need as "a condition or symptom whose treatment or diagnosis is not addressed adequately by available therapy[vi]." According to non-profit rare disease advocacy and research group Every Cure, "less than 22% of the 18.5K recognized diseases in the world have FDA-approved treatments[vii]."

> **WHOEVER INVENTS OR DISCOVERS ANY NEW AND USEFUL PROCESS, MACHINE, MANUFACTURE, OR COMPOSITION OF MATTER, OR ANY NEW AND USEFUL IMPROVEMENT THEREOF, MAY OBTAIN A PATENT THEREFOR, SUBJECT TO THE CONDITIONS AND REQUIREMENTS OF THIS TITLE.**
>
> *35 U.S. CODE § 101 - INVENTIONS PATENTABLE*

Patented Medicines. "[A]fter John J. Powers assumed the presidency of Pfizer in 1965, he invited the respected management consultant Peter Drucker to evaluate the company's structure and approach. Drucker concluded that 'Pfizer acted like a classic manufacturer," and he advised the firm, "What you are making and selling is knowledge, and manufacturing is incidental[viii].'"

Since that time the increasing complexity of advanced biopharmaceutical manufacturing means that the physical production of medicines, too, is an exercise in innovation, making Drucker's core insight all the more relevant: The development production, and delivery of pharmaceutical innovation is a knowledge-intensive industry. That's where patents come in.

The statutory term of U.S. patent protection is 20 years, a period of exclusivity intended to give the innovator time to earn revenue on large investments in research and development, clinical trials, regulatory approvals, and innovative manufacturing processes before facing lower-cost generic competition. In practice, the 20-year patent term yields innovators a much shorter period of effective market exclusivity in which to earn a return on investment. While patents are in place, medicines can be sold at a price that reflects the costs of the innovation that makes them possible. Soon, competitors who have not shared in the expense of drug discovery are permitted to replicate the innovator's work and offer an identical medicine for sale at a price more directly associated with the costs of physically reproducing the medicine.

Generic Medicines. The term "generic" carries dual meanings for medicines, denoting a therapy that may be off-patent, as well as unbranded. According to the Association for Accessible Medicines (AAM), the U.S.-based trade association representing the generic pharmaceutical industry, "When a medicine is first developed, the pharmaceutical company that discovers and markets it receives a patent on its new drug. The patent usually lasts for 20 years, to give the originating company a chance to recoup its research investment. After the patent expires, a generic version of the drug may become available. Generics are marketed under the drug's chemical, or "generic," name and meet the same FDA quality and effectiveness standards as the original." "Drug research is costly," AAM continues, "and patent protection gives brand-name manufacturers at least 20 years to recover research & development costs—costs that generic manufacturers do not have to recoup[ix]."

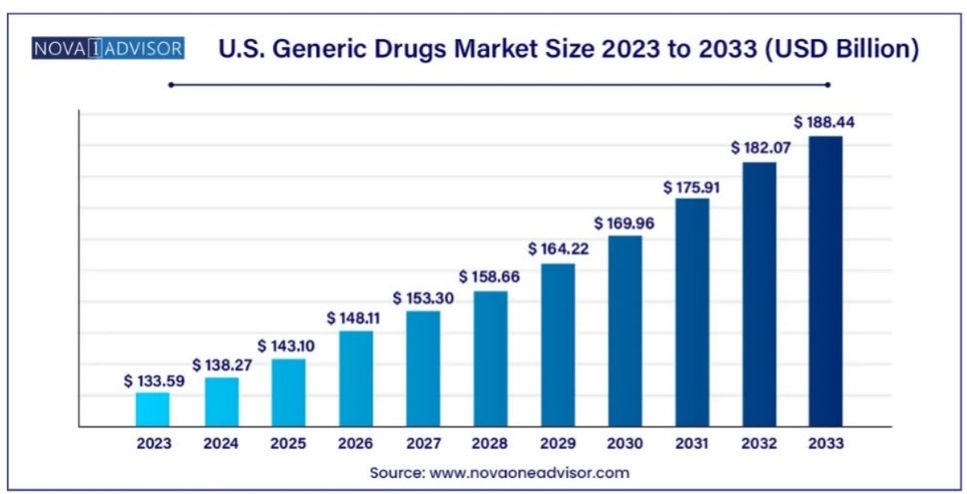
In reality however, "Overall, most new drugs receive about 12 to 16 years of market exclusivity[x]."

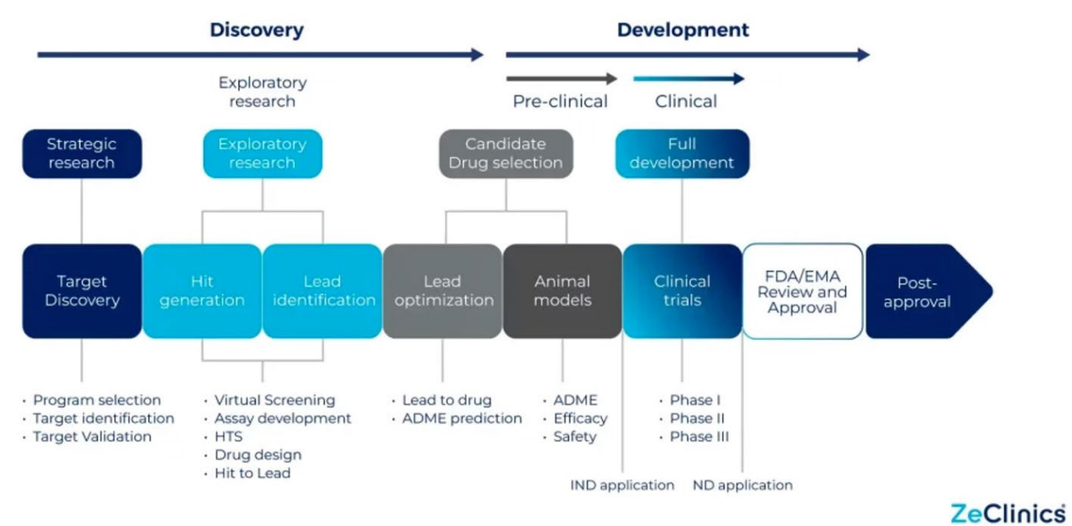
Generic medicines account for approximately 93% of U.S. prescriptions[xi], and 93% of generic prescriptions are filled at $20 or less with an average co-pay of just $6.16[xii] , representing the vast majority of prescriptions filled by Americans. The relatively small share of remaining prescriptions, for innovative therapies that address previously unmet medical needs, represent the cutting edge of biopharmaceutical technology.

Making Medicines. In historical terms, the biopharmaceutical sector occupies a relatively new area of technology: "Aspirin (acetylsalicylic acid), an organic compound that does not occur in nature, was first synthesized in 1899[xiii]," says Wikipedia. "[I]ts formulation is regarded as the foundation of the modern pharmaceutical industry[xiv]."

Human biology—no less than the ocean depths, outer space, quantum computing, or AI—has many mysteries yet to be revealed. "Despite advances in biotechnology and understanding of biological systems, drug discovery is still a lengthy, costly, difficult, and inefficient process with a high attrition rate of new therapeutic discovery[xv]."

The development of a new medicine or therapy to address an unmet medical need is a multi-stage process. Researchers must first identify a specific biological target that is the proximate cause of an underlying health problem. That's just the start. Numerous technical challenges must be overcome along the way, often involving pioneering work in biology, chemistry, and engineering, among other specializations. Patents enable the significant capital expenditures that are often necessary to





> [M]ULTIPLE PATENTS ASSOCIATED WITH A SINGLE MARKETED PRODUCT ARE ... A COMMON PRACTICE IN MANY INNOVATIVE INDUSTRIES, ESPECIALLY FOR COMPLEX PRODUCTS.

advance the state of the art at every stage of drug discovery and secure the sought-after biomedical outcomes.

Unfortunately, the long and complex work of drug discovery may increasingly be hampered by policy constraints that would artificially limit the patent rights of innovators. Numerous bills seek to limit innovator rights to the various discoveries that collectively comprise a complex biopharmaceutical product.

The main premise of such measures seems to be a misapprehension of patent scope, suggesting the view that holding more than a single patent for a single product must be anti-competitive. This flies in the face of technological, economic, and legal reality, where patents cover inventions and discoveries rather than end-products. The ubiquitous mobile phone by one estimate contains 250,000 patented inventions[xvi], each adding a unique capability or solving a technical problem, which collectively enable the whole phone to work as intended.

Similarly, biopharmaceutical products are successful only when they can overcome a range of complex biological challenges that stand in the way of delivering a safe and effective dose of the right medicine to precisely the right place in the body, in precisely the right manner, to treat or cure a particular disease in a particular patient. Such biological challenges are not addressed by a single mechanism, and therapies and cures are not developed all at once; they are the result of a process of living innovation that requires ongoing investment enabled by patents on new discoveries along the way.

Throughout the innovation lifecycle appropriate use of patents and related regulatory exclusivities enable investment and risk-taking at each stage of drug development. While a single product may be subject to multiple patents, their unique claims, and the limits on their scope, duration and overlap, help illustrate why numerous patents may cover a single successful medicine.

What Goes Into a New Medicine?

Subject Matter Compound/Biologic Candidates

"The first step is to analyze biological mechanisms and determine how modifying a specific protein or pathway could produce a therapeutic effect," says Miriam Martinez. "[S]mall-molecule compounds or biological therapies are screened to identify initial candidates acting on the target. ... [L]ead optimization in drug discovery enhances their potency, selectivity, and pharmacokinetic profile to ensure they meet therapeutic requirements, revealing potential drug candidates." **Composition of Matter patents** are directed to the specific chemical or biological combinations that form a medicine.

Delivery Systems

"Drug delivery systems are engineered technologies for the targeted delivery and/or controlled release of therapeutic agents," says the NIH. "Medications can be taken in a variety of ways—by swallowing, by inhalation, by absorption through the skin, or by intravenous injection. Each method has advantages and disadvantages, and not all methods can be used for every medication. Improving current delivery methods or designing new ones can enhance the use of existing medication." **Delivery System patents** often apply.

Dosage

Optimizing dosage is critical to both the efficacy and safety of a new medicine. A dose-finding study identifies the range between no-effect and maximum safe effectiveness, according to Martinez. Then taking tolerability into account, the optimal therapeutic dose range can be selected and duration of action tested, including for sub-groups of patients such as pediatric or the elderly. **Formulation patents,** including the use of secondary ingredients that may control the release of the active pharmaceutical ingredient, may apply.

Testing and Regulatory Approval

FDA regulates the testing and marketing of new medicines, requiring innovators to conduct rigorous multi-phase clinical trials to demonstrate a medicine's safety and efficacy before it can be offered for sale. Clinical trials in humans increase in size, cost, and complexity at each successive phase. Paying it forward, patents on previously launched products allow for the risk and expense of clinical trials, while **regulatory data protection** provides a period of exclusivity for business proprietary information.

Manufacturing and Supply Chains

Industry trade association PhRMA says, "Building a new manufacturing facility can cost up to $2 billion and take 5 to 10 years before it is operational, including the time and costs related to comply with various regulatory requirements," adding that new product lines require production engineering and scale-up, validation, stability protocols and regulatory filings, which can take several years. **Manufacturing process patents** are critical allow the investment in the up-front capital expenditures.

A Policy Solution

More and Better Medicines. U.S. firms invest $150 billion[xvii] annually in biopharmaceutical R&D. What do Americans get in return? Recently, it's been GLP-1's for weight loss, Covid-19 vaccines, Hepatitis C cures, HIV PrEP at 99% effectiveness: For anyone suffering from a rare or as yet untreatable disease, this is an era of unprecedented hope. Highly effective therapies and even cures are coming fast and furious. The first goal of policy should be to keep them coming.

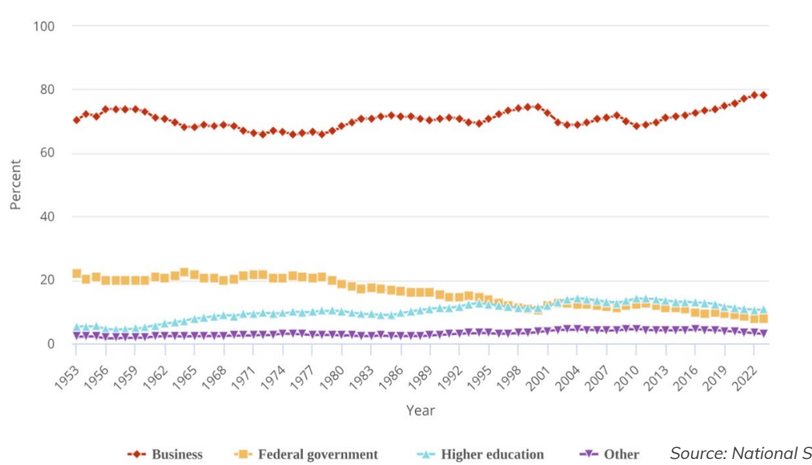
Lifecycle Investment. A lifecycle view of innovation illustrates both the complexity of drug discovery and the importance of patents at each stage:

- Basic Research expands human knowledge and our grasp of human biology;
- Applied Research points new knowledge toward a specific problem like a biological target causing disease;
- Product Development is where a promising therapy is formulated and optimized for drug delivery;
- Testing and Regulatory Approval challenge and refine a medicine to ensure its safety and efficacy;
- Commercialization processes overcome engineering hurdles to reproduce a therapy at scale; and,
- Living Innovation sees scientists working and companies investing to continually perfect a medicine, making it safer, more effective, and more broadly applicable to new patients and new uses.

According to the National Science Foundation, "The business sector is by far the largest U.S. R&D-performing sector, accounting for 78% of U.S. R&D performance in 2023, followed by the higher education sector (11%) and the federal government (8%).[xviii]" Private sector investment in excess of $150 billion per year provides the lion's share of the funding in a robust biopharmaceutical innovation ecosystem, where various stakeholders in government, academia, and industry, all contribute critical R&D functions to the lifecycle of innovation.

National Center for Science and Engineering Statistics | NSB-2025-7

Figure DISC-5. U.S. R&D expenditures, shares by performing sector: 1953–2023



Source: National Science Foundation

Top Five Drug Launches of the 21st Century

1. **Adcetris** – The mode of action of this drug is a thing of beauty - an antibody that carries the drug directly to the individual cancer cells to kill them. Healthy cells are not harmed. Such simplicity belies the incredible science behind its development.
2. **Gleevec -** A chronic myeloid leukemia diagnosis in the last century was a fairly certain death sentence. Existing treatments were harsh and invasive. Enter Gleevec: a once or twice daily pill and bingo – disease controlled. Its mode of action description: 'programmed cell death'.
3. **Atripla -** The pharmaceutical industry transformed the deadly AIDS disease into a manageable chronic condition in only a few years. Early treatments were unpleasant. Once highly active anti-retroviral therapy was identified, the race was on to deliver this complex regimen as conveniently as possible. Hence, Atripla – one pill, once a day, an effective trilogy of anti-retroviral drugs. For the HIV-positive person subject to complex pill regimens, Atripla was a game changer.
4. **Keytruda** – Until recently, oncologists tried to eke out a few more weeks or months of life for patients with advanced cancers of virtually any description using highly toxic regimens. That's all they had. The kind of efficacy results delivered by a Keytruda-enhanced chemotherapy regimen - they wouldn't have believed it possible.
5. **Humira** – This was the first monoclonal antibody blockbuster. It transformed the lives of patients who had had little relief from chronic diseases such as RA, Crohn's and psoriasis. It now has 14 indications, which is a testament to its incredible utility.

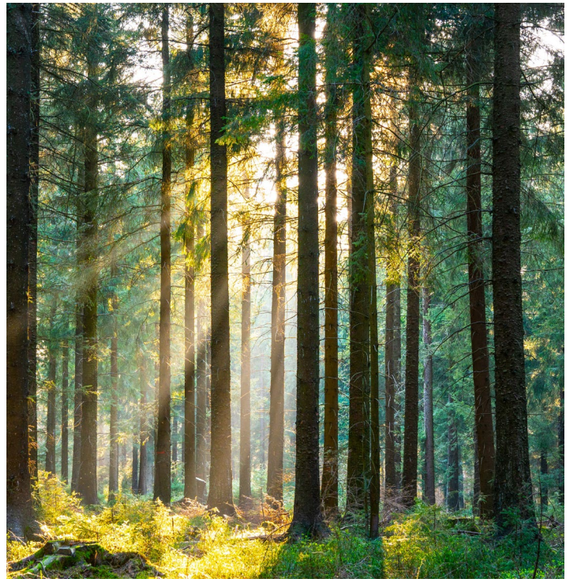
Neil Dickinson, Dice News (excerpted from the original and edited for length)
https://www.dice-comms.co.uk/perspectives/dice-news/top-five-drug-launches-of-the-21st-century/

By creating intellectual property assets that are protectable, investable and transferable, patents earned at each stage of R&D enable the transfer of technology among stakeholders and firms that specialize at various phases of the innovation lifecycle along a path from basic research to commercialization of a new therapy. When patent rights are available, reliable and predictable, they form a legal and commercial basis for the joint ventures, acquisitions, or IP licenses that keep a new technology moving forward and stakeholders working together.

A Healthy Ecosystem[xix]. A forest provides an apt metaphor for the workings of the biopharmaceutical innovation ecosystem. The canopy of a healthy forest seen from above appears to be an impenetrable thicket of green. A ground level view provides a starkly different outlook of a place where diverse plant and animal life coexist. Above the ground and below the canopy, trunks branch and branch again, drawing sustenance from their roots, reaching for the sunlight that catalyzes life, and providing the trees a place in which to bear fruit and seed the next generation of abundance.

Just as a forest's health is contingent on symbiotic interactions among numerous plants, animals, and insects, the biopharmaceutical innovation ecosystem, too, connects a wide universe of stakeholders, including federal laboratories, research universities, start-ups and corporations, venture capitalists and financial markets, regulators, hospitals, doctors, and patients. In this ecosystem, new chemical, molecular, or biological entities—the core of a medicine—are patented, when discovered, as novel compositions of matter.

Such composition of matter patents form the main trunks of patent families that will branch and



PERSPECTIVE: DO YOU SEE AN IMPENETRABLE THICKET OR A THRIVING HABITAT?

branch again as researchers perform the arduous work of engineering practical applications for promising early-stage scientific discoveries. The applications of these discoveries often extend across diverse therapeutic areas and delve into variations on the manufacturing, formulation, dosage, modes of delivery, timing, and tolerability of the medicine. Each foray in a new direction requires dedicated outlays of time and money to pioneer solutions, as well as to demonstrate the safety and efficacy of the resulting solutions through expensive clinical trials and other regulatory approval processes.

Where patent rights are sufficiently available and reliable they provide a basis for investment in the long-term, high-risk, resource-intensive work of curing disease. Just as a tree's capillaries enable sunlight to draw water and nutrients through its entire system, patent rights to novel discoveries and inventions provide conduits for the investment that catalyzes diffusion of knowledge and transfer of technology throughout the innovation lifecycle. Just as trees need repeated exposure to sunlight, biopharmaceutical innovations require round after round of sustained investment.

Patent assets, as well as protection of trade secrets, provide a common currency whereby would-be partners can negotiate working arrangements with a clear understanding of the value each brings to a collaboration, a license, or a sale. Partnerships thrive and funding and know-how move seamlessly among stakeholders in the innovation ecosystem when patents ensure the rights of diverse parties are secure, transparent and reliably enforced in a rule of law environment.

Living Innovation. Biopharmaceutical innovation doesn't end with discovery of a promising new chemical entity or biologic and its corresponding composition of matter patent. This is merely the main stem from which researchers branch out in fruitful directions to seek the specific solutions that will safely and effectively deliver this therapeutic molecule to just the right place—and none of the wrong places—in the patient's body.

The patentability of living innovations—the fruits of investment made even after a new medicine has met with regulatory approval—enables researchers to continue to work to perfect a medicine, beyond the discovery of a core composition of matter. Further patents in turn permit further research

and clinical trials to continue and make treatments increasingly effective over time for a broader range of patients.

Living innovation, enabled by well-functioning patent law and administration, is making more breakthrough medicines available to more patients and children in more therapeutic areas. Yet a great deal of criticism is leveled at biopharmaceutical innovators focusing on so-called "post-approval" innovation, which takes place after the FDA has recognized the medicine as safe and effective and approves it, and usually before the patent on the subject matter compound expires.

Post-approval innovations, often dismissed by industry critics as trivial, can be highly advantageous to patients. Investments in post-approval innovation may make a medicine safer and more effective for a broader group of patients, enable a medicine's use in children, or even uncover new conditions for which a given product may have a therapeutic benefit.

The costly and laborious work of building on a basic drug discovery conveys additional rights to the innovator, which the U.S. Patent & Trademark Office (USPTO) has shown[xx] do not materially affect the duration of the innovator's exclusive rights. On the contrary, without patents on living innovation, what's left of the biopharmaceutical ecosystem is a forest of stunted trees that are no longer able to bear fruit.

Living Innovation

"In the cycle of innovation, inventors build upon the knowledge and advancements of those that came before them. Even today, patents continue to be granted for eyewear when the claimed invention meets the standards for patentability even though eyewear itself has existed for centuries. Innovative improvements in eyewear are conceptually analogous to innovative improvements in the pharmaceutical field as both ground-breaking and incremental innovations can improve the product to the benefit of the user. For example, a known active pharmaceutical ingredient with a new extended-release formulation that reduces the necessary dose frequency may be shown in clinical trials to benefit a patient by, among other things, simplifying dosing regimens and improving adherence to the prescribed drug, and a new use of an old drug may be shown in clinical trials to provide a new, effective treatment for a disease. Such improvements, when deemed patentable, are entitled to patent protection, which is limited in scope to the patentable improvement. Importantly, once the original patent expires, the public may use the technology covered by the expired patent. Patents on the improvements only prevent the public from using the new technology until the new patents expire."
(emphasis in the original)

U.S. Patent and Trademark Office | Drug Patent & Exclusivity Study

Debunked

In the wake of the pandemic, biopharmaceutical innovators were besieged by claims that vital prescription medicines were eluding competition as a result of patent proliferation and unfair extension of patent terms. Responding to a request from Senator Thom Tillis (R-NC), the U.S. Patent and Trademark Office (USPTO) undertook a fact-based examination and corrected the record with a clear, empirical analysis:

- For its Drug Patent and Exclusivity Study, USPTO selected **25 medicine**s that were emblematic of the lifecycle for innovation of new therapies and the subsequent transition to generic competition.
- USPTO examined all patents listed in the Orange Book for each of the 25 medicines—among them the "most prescribed" and "top grossing" prescription medicines of the study period—and found that **none** of the medicines was afforded more than 3 to 16 years of total market exclusivity – **well short of the 20-year patent term.**
- The findings repudiate accusations of patent manipulation that have been made by activists and relied upon by Congress who **claimed innovators were obtaining patent exclusivity periods for as much as 49 years.**
- The inescapable takeaway from the USPTO study is that **activists manipulated data** to inflate the effects of patents and other exclusive rights on competition.

Source: Debunked: USPTO Findings Should End False Pharma Patent Narratives, Patrick Kilbride, IPWatchdog.com, October 18, 2024, https://ipwatchdog.com/2024/10/28/debunked-uspto-findings-end-false-pharma-patent-narratives/

Debunking Patent Myths. Threatened by a fatally flawed vision of one patent per product, and the misguided mindset that anything expensive must be overpriced, biopharmaceutical innovation is under attack on many fronts, from drug price controls, to government "march-in rights," foreign reference pricing, global IP waivers, and forced technology transfers.

The punitive legislative proposals that result stigmatize biopharmaceutical innovation in terms such as product "hopping" or patent "thickets," accompanied by administrative measures to limit the availability of patents for improvements on existing products. These initiatives thoroughly misrepresent the role of patents in innovation and threaten the unparalleled productivity of the U.S. biopharmaceutical ecosystem.

Pointing to life-saving products like inhalers and insulin, some activists have claimed that technological advances secured in recent years are unworthy of patent protection. In the case of inhalers, one Senate hearing witness[xxi] repeatedly suggested there had not been meaningful improvements to these products "since 1956." Yet a doctor treating COPD, diabetes, or many other ailments could be liable for malpractice—and likely criminal prosecution—if they prescribed the standards of care today that were in use in 1956.

Such criticisms over-simplify, devalue, and dismiss as "obvious," the difficulty and significance of securing improvements to the methods and mechanics of biopharmaceutical manufacturing, formulation, dosage, and delivery. What's more, they ignore the consistent and principled application of U.S. law over many decades: The U.S. Patent & Trademark Office says simply that patents on improvements to existing products **do not extend the life of the claims** made by the original patent; they only cover the specific claims on the improvement. The Congressional Research Service adds, "If the original patent has expired but the improvement patent has not, permission from the improvement patentee is needed to practice the improved version, but as a matter of patent law, *any person is free to make and use the original, unimproved version.*[xxii]" (emphasis added)

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Page One Call-Out Box - "Enormous Investments"

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The Center for American Principles is a 501(c)(4) non-profit issue advocacy organization that advances sound policy solutions based on core principles to tackle the country's most critical challenges.

Our mission is to protect and promote free markets and conservative values around individual freedoms,

free enterprise, limited government, the rule of law and a strong national defense.

We bring awareness to the increasing threats facing Americans by government overreach, bureaucratic control, international bad actors, and intrusions on our personal liberties.

The Center for American Principles drives policy debates by educating and mobilizing the American public in furtherance of our mission.

Our leadership and advisors have a combined decades of experience in business, government, grassroots, and communications— which allows us to effectively develop and communicate public policy solutions to Congress, the Executive Branch, and the American people.

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