Pharmaceutical "Patent Thickets"

Why do pharmaceutical companies seek multiple patents on one medicine? Are they just creating "patent thickets"?

Myth

Critics claim that drug companies obtain an excessive number of patents on the same medicine with little scientific justification, purely to build a dense "patent thicket" that blocks competitors. Some propose that one patent ought to be enough, others put forward reasons to question every patent beyond the first, while still others see later-filed patents as a carefully timed strategy calculated to stifle competition (Feldman, 2018; Gurgula, 2017; Goode & Chao, 2022).

Reality

Medicines aren't patented; inventions are. While some medicines might contain just a single invention, that's rarely the case in practice. Developing a medicine is a journey of several years through many scientific challenges, not a single, one-and-done "Eureka!" moment. This journey from lab to patient proceeds through a series of inventive steps, with each solution requiring further investment of resources that can't happen without the chance to obtain the security of a patent (Lietzan, 2019; Holman, 2017).

Throughout this journey, patient needs and scientific problems – not legal strategy – drive innovation. Patent attorneys don't direct research; they follow it. When scientists solve critical problems, the resulting innovations merit patent protection because they represent genuine progress. Each is a technical solution to a technical problem (Holman, 2017).

These innovations occur both before and after regulatory approval.

Some patents protect pre-approval discoveries that enable drugs to work safely and effectively for patients. Yet critics examining successful drugs see only patent counts, not these enabling innovations. The harsh reality is that approximately 90% of drug candidates fail in clinical trials, most commonly due to efficacy issues (52%) or safety concerns (24%) (Harrison, 2016; Hay, 2014). Each pre-approval patent on a successful medicine typically represents a solution to a problem that prevented failure.

Other patents protect post-approval improvements that enhance patient outcomes such as new uses, improved delivery methods, or better formulations. Critically, these later patents don't block generic versions of the original drug product once its core patents expire. This distinction matters because critics who count all patents as "blocking" competition fundamentally misunderstand or misrepresent how the system works.

For a successful drug candidate, solving problems with efficacy and safety often requires inventing solutions to problems that might have otherwise caused the drug to fail (Sun, 2022; Harrison, 2016; Hay, 2014). Patents on these solutions represent hurdles that had to be overcome in the complex journey from laboratory to patient.

This accumulation of inventions mirrors innovation in other fields. We readily understand why cars and computers contain dozens of separately patented innovations that improve over time. Most medicines are no different – they also are collections of inventions, just packaged in a less visible form.

The innovation timeline below reveals why multiple patents are both inevitable and beneficial.

Early R&D and development

A medicine's development typically begins with identifying a promising, novel compound that might eventually become a treatment. However, in its original form, it may be ineffective or even harmful inside the human body. Turning that compound into a viable treatment requires further innovation. Researchers must invent optimal formulations, delivery methods, dosing regimens, and manufacturing processes to ensure safety and efficacy. These innovations represent distinct technical solutions to scientific challenges (Sun, 2022; Lietzan & Acri, 2020; Holman, 2017).

Clinical use and further improvements

Innovation doesn't stop once clinical trials begin. Companies continue to study and improve medicines based on early patient experience and feedback in clinical trials. This innovation can improve safety and efficacy and, in some cases, solve challenges that would otherwise prevent a medicine from reaching patients. These solutions deserve protection through patents.

Post-approval innovation

Innovation continues after regulatory approval and initial market launch. Drugs are often first tested and approved for conditions where other treatments are poor or non-existent – exactly where patient need and economic justification are greatest. However, once a drug is de-risked through demonstration that it is safe and effective for one patient population, further research and innovation to bring the drug to additional patient populations makes economic, ethical, and scientific sense (Roin, 2014).

Post-approval research yields real patient benefits in several ways. Innovators may expand treatments to related patient populations – for example, testing a cancer drug proven effective for kidney tumors on other cancer types. They may also discover entirely different therapeutic applications, finding that drugs work for completely unrelated diseases. Additionally, companies develop improvements that make treatment easier and more effective for patients, such as extended-release formulations or converting lengthy infusions to simple injections.

The scale of this innovation is significant: between 2008-2018, roughly three-quarters of oncology drugs secured at least one additional FDA-approved use beyond their initial indication (Lietzan & Acri, 2020). Far from being strategic patenting gimmicks, these advances are often lifesaving – a new combination therapy or safer variant can dramatically improve outcomes (Lietzan & Acri, 2020; Holman, 2017; Roin, 2014). Without the ability to patent follow-on innovations, companies would have far less incentive to invest in finding new uses or improvements for existing drugs.

Patent quality and scope

Each patent must meet rigorous standards of novelty and genuine inventiveness. Critics often dismiss drug modifications as routine chemistry, but this oversimplifies complex innovation and the investments that are required to deliver it. If changes aren't inventive, they don't deserve patents, and they won't get them because patent offices screen patent applications for inventiveness. If they're inventive but trivial, they pose minimal barriers to generic competition (Holman, 2017). Many modifications, however, are both inventive and significant.

Consider Plavix, an important blood thinner. It was invented by researchers using methods that were themselves well known but whose outcomes were far from predictable. A generic manufacturer challenged Plavix's patents in more than one jurisdiction, claiming they were not inventive because of the familiarity of the technique used in research – ignoring the clear inventiveness of the drugs thereby created. Courts in multiple jurisdictions upheld these patents, recognizing that inventiveness lies in the results achieved, not the methods used (Holman, 2017). Scientists had to engage in substantial experimentation to achieve this rare and unexpected result.

Patient-centered improvement: From infusion to injection

One example of valuable innovation is reformulating medicines to improve how patients receive them. Many biologic drugs initially require lengthy intravenous infusions at clinics or hospitals. Companies therefore have developed subcutaneous injection versions that patients can receive in minutes in a doctor's office or at home.

These patented innovations have been dismissed as trivial or unneeded by critics. This criticism overlooks both the science and the tremendous benefits to patients.

For patients, infusion days can be physically and emotionally taxing – traveling to infusion centers, sitting uncomfortably for hours, and coping with side effects. The process disrupts work schedules and burdens caregivers.

In contrast, subcutaneous injections offer a faster, less invasive alternative. For the breast cancer drug trastuzumab, a 5-minute subcutaneous injection proved just as effective as the IV formulation – and was preferred by over 80% of patients (Pivot et al., 2017).

The simplicity gave patients greater autonomy and reduced the sense of being "tied to a treatment chair." In some instances, the subcutaneous form can reduce the reactions experienced with infusion. These innovations aren't cosmetic conveniences – they improve patients' lives in tangible, measurable ways.

These innovations also aren't trivial scientifically. Reformulating large molecules for concentrated injection presents significant technical challenges compared to IV delivery, requiring research and innovation to solve. Importantly, patents on these improvements protect the specific innovation without blocking generic versions of the original formulation, supporting both innovation and generic competition.

The bottom line

Multiple patents typically reflect cumulative innovation driven by patient needs, not abuse of the patent system. Each represents an advance in the complex process of developing and improving modern medicines. In a world of increasingly complex science and healthcare, such patents ensure that innovators can keep investing to solve problems for patients, step by step.

References

DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics, 47, 20-33. https://doi.org/10.1016/j.jhealeco.2016.01.012

Feldman, R. (2018). May your drug price be evergreen. Journal of Law and the Biosciences, 5(3), 590-647.

Goode R, Chao B. (2022). Biological patent thickets and delayed access to biosimilars, an American problem. J Law Biosci. 9(2),1-24.

Gurgula, O. (2017). Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies – Two Different Concepts Sharing Similar Features. IIC – International Review of Intellectual Property and Competition Law. 48, 385–404.

Harrison, R. K. (2016). Phase II and phase III failures: 2013-2015. Nature Reviews Drug Discovery, 15(12), 817-818. https://doi.org/10.1038/nrd.2016.184

Hay, M., Thomas, D. W., Craighead, J. L., Economides, C., & Rosenthal, J. (2014). Clinical development success rates for investigational drugs. Nature Biotechnology, 32(1), 40-51. https://doi.org/10.1038/nbt.2786

Holman, C. M. (2017). In defense of secondary pharmaceutical patents: A response to the UN's guidelines for pharmaceutical patent examination. Indiana Law Review, 50(3), 759-801. https://doi.org/10.18060/4806.1153

Lietzan, E. (2019). The "evergreening" metaphor in intellectual property scholarship. Akron Law Review, 53(3), 805-871.

Lietzan, E., & Acri, K. M. L. (2020). Distorted drug patents. Washington Law Review, 95, 1317-1385.

Pivot, X., Spano, J. P., Espié, M., Cottu, P., Jouannaud, C., Pottier, V., Moreau, L., Vie, J. M., Piprot, C., Romieu, G., Serin, D., Dohollou, N., Hardy-Bessard, A. C., Bachelot, T., Jouannaud, C., Arnaud, A., Mouret-Reynier, M. A., Leheurteur, M., & Fumoleau, P. (2017). Patients' preference of trastuzumab administration (subcutaneous versus intravenous) in HER2-positive metastatic breast cancer: Results of the randomised MetaspHer study. European Journal of Cancer, 82, 230-236.

Roin, B. N. (2014). Solving the problem of new uses for existing drugs. Working Paper. http://nrs.harvard.edu/urn-3:HUL.InstRepos:11189865.

Sun, D. (2022, February 23). 90% of drugs fail clinical trials -- here's one way researchers can select better drug candidates. The Conversation. https://theconversation.com/90-of-drugs-fail-clinical-trials-heres-one-way-researchers-can-select-better-drug-candidates-175443

Extract from Pharmaceutical "Patent Thickets" authored by **Mark Schultz**, The IP Policy Institute, The University of Akron (IPPI), and **Jennifer Brant**, Innovation Insights, with **Douglas Park**, IPPI. September 2025.
unpackingip.org/biopharma