February 25, 2026

Essential Patent Protection Areas for Pharma Startups - Secondary Patents

by Christopher James Garcia, Ph.D.

This entry, Part IV in our multi-part series, examines the strategic importance of secondary patents in the pharmaceutical industry, with a focus on how follow-on inventions, such as improved formulations, combination therapies, and new indications for existing compounds, can extend market exclusivity and create additional value streams. We explore the ways in which secondary patents help companies protect incremental innovations, delay generic competition, and incentivize further research and development. While acknowledging ongoing debates surrounding the use of secondary patents, this installment provides practical insights for stakeholders seeking to leverage intellectual property for sustained competitive advantage and growth.

Introduction to Secondary Patents

Secondary patents have become a cornerstone of pharmaceutical intellectual property strategy, particularly in the context of follow-on inventions. Unlike primary patents, which typically claim a novel chemical entity or active pharmaceutical ingredient, secondary patents focus on improvements and modifications to existing compounds. These may include enhanced formulations, combination therapies, or newly discovered uses. The pharmaceutical industry faces increasing pressure to innovate and maximize value, and this pressure is exceedingly present for startups seeking to gain a foothold. Secondary patents offer a critical tool for extending the commercial lifecycle of valuable drugs.

Improved and Novel Formulations

One common category of secondary patents involves improved or novel drug formulations. Pharmaceutical companies often invest significant resources in developing new delivery methods, such as extended-release tablets, transdermal patches, or more stable liquid preparations. These advancements can lead to secondary patents that protect the unique formulation, even after the primary compound’s patent has expired. Such patents can be essential for maintaining market exclusivity, especially when improved patient compliance or therapeutic outcomes result from the new formulation.

Use Case 1: “Chiral Switch”

AstraZeneca® strategically leveraged the concept of a “chiral switch” to extend the commercial success of its blockbuster drug Prilosec® (omeprazole), a proton pump inhibitor (PPI) widely prescribed for heartburn, gastroesophageal reflux disease (GERD), and related conditions. During the 1990s, Prilosec® achieved tremendous market dominance, generating $4 billion in sales in 1999 alone. As the original patent on omeprazole neared expiration, and with generic competition looming, AstraZeneca® isolated the (S)-isomer from the racemic mixture of omeprazole, developing and patenting this purified form as Nexium®. By obtaining new formulation patents for Nexium®, AstraZeneca was able to maintain exclusivity in the acid reflux market and effectively extend its market dominance for an additional decade.

Combination Therapies

Combination therapies represent another fertile ground for secondary patent protection. By combining two or more existing compounds into a single treatment regimen, pharmaceutical companies can create new therapeutic options and address unmet medical needs. Secondary patents may cover the specific combination, the dosing regimen, or even synergistic effects that enhance efficacy or reduce side effects. This strategy not only extends the exclusivity period for the underlying compounds but also creates additional revenue streams through differentiated product offerings maximizing licensing opportunities for startups.

Use Case 2: “Supramolecular Complex”

Novartis® developed and patented valsartan, an angiotensin II receptor blocker (ARB) indicated for hypertension and heart failure, as well as sacubitril, a neutral endopeptidase (NEP) inhibitor used in the management of chronic heart failure. Building on these innovations, Novartis® created a novel formulation by combining the two active ingredients into a supramolecular co-crystal, marketed as Entresto®. This fixed-dose combination leverages the complementary mechanisms of both compounds, resulting in enhanced therapeutic efficacy for heart failure patients and provided the basis for new secondary patents that extended market exclusivity beyond the original patents for valsartan and sacubitril.

New Indications and Uses

Secondary patents can also be obtained for new indications or uses of established drugs. Startups benefit from the reality that ongoing research reveals additional therapeutic benefits for known compounds, which can be capitalized upon by filing for patent protection on these newly discovered applications. For example, a drug originally approved for cardiovascular disease may later be found effective in treating certain cancers or autoimmune disorders. These patents provide a legal basis for exclusivity in the new indication, incentivizing further research and revenue streams for investment in drug repurposing.

Use Case 3: "Heart Treatment to Hair Loss"

Upjohn® initially patented oral minoxidil (marketed as Loniten®) in the 1960s as an antihypertensive agent for the treatment of high blood pressure. During clinical trials, both researchers and patients observed a notable side effect: excessive hair growth and reduced hair loss. Recognizing the commercial potential of this unexpected outcome, Upjohn® subsequently developed and patented a topical formulation of minoxidil specifically for the treatment of androgenetic alopecia (male and female pattern baldness), which was brought to market as Rogaine®. This strategic repurposing allowed Upjohn® to secure new patents and extend the commercial life of minoxidil beyond its original cardiovascular indication.

Extending Exclusivity and Value Streams

The strategic use of secondary patents enables pharmaceutical startups to extend market exclusivity beyond the expiration of primary patents. This approach not only safeguards revenue but also supports continued innovation by funding additional research and development efforts. Secondary patents can thus create multiple, overlapping value streams throughout a drug's lifecycle.

Challenges and Controversies

Despite their advantages, secondary patents are not without controversy. Critics argue that they may contribute to "evergreening," where incremental changes are used to unjustifiably prolong exclusivity and delay generic entry. Regulatory authorities and courts have increasingly scrutinized secondary patents to ensure that they meet the standards of novelty and non-obviousness. Nonetheless, when properly utilized, secondary patents remain a legitimate and powerful mechanism for encouraging pharmaceutical innovation and investment.

Examples of Secondary Patents in Pharmaceuticals

Secondary Patent Type	Description	Example Application
Novel Formulation	New delivery method or composition	Extended-release tablet
Combination Therapy	Multiple drugs combined	Fixed-dose combo for HIV treatment
New Indication/Use	New disease or condition	Cancer therapy used to treat osteoporosis

Kilpatrick's Guidance on Leveraging Secondary Patents

At Kilpatrick, our Intellectual Property attorneys are committed to guiding pharmaceutical innovators and life sciences companies through the nuanced landscape of secondary patent protection. We collaborate with R&D teams and business leaders to identify, secure, and maximize IP assets related to improved formulations, combination therapies, and novel uses for existing compounds. Whether you are seeking to extend market exclusivity, develop robust patent portfolios, or respond to regulatory and competitive challenges, our team delivers practical, business-focused counsel tailored to your organization's strategic goals. Additionally, we work seamlessly with trusted partners across global jurisdictions to ensure your secondary patents are protected and enforced wherever your innovations reach. For more information on developing a comprehensive secondary patent strategy or to connect with our experts for customized support, please visit our website or contact us directly.