

PATENTS DRIVE INNOVATION OF BOTH NEW AND IMPROVED PRODUCTS

The Real Facts About “Evergreening”

In the public debate over drug costs, there is a lot of discussion about so-called “evergreening.” While this is not a precisely defined term, most often evergreening refers to the false notion that drug manufacturers make minor changes to their existing drugs, obtain new patents or regulatory exclusivity for these changes, and thereby extend their market “monopoly” or create “patent thickets” that block competition.

Let’s look at the real facts.



First, generics are coming to market no later than they have for decades.¹

If evergreening were the increasingly problematic phenomenon alleged by critics of the drug development industry, we’d expect to see increasing barriers to generic entry and longer brand “monopoly” time periods. The data, however, shows the opposite—the time from original FDA approval to generic entry has averaged about 13.5 years since 1995 without any meaningful change—if anything, some studies show that the brand exclusivity period may be shrinking.

Generics also are dominating the market faster than ever before. **Within 6 months of generic entry, they now control 80% of the market for a copied drug.²**

~90%
of prescriptions
in the U.S. are
now being filled
with generics.



Second, there is nothing unusual about a product having multiple patents:

- ▶ Titleist Pro V1x Golf Balls **60 patents³**
- ▶ BlackBerry KEY2 LE **242 patents⁴**
- ▶ Nike Flyknit Shoe Technology **300+ patents⁵**
- ▶ Firefly Light Up Timer Toothbrush **15 patents⁶**
- ▶ LG Spectrum VS930 Smartphone **626 patents⁷**
- ▶ Bose Quiet Comfort 20 and 20i Headphones **35 patents⁸**
- ▶ Honeywell Xenon 1900 Series General Duty Scanner **91 patents⁹**

That’s because innovation doesn’t stop once a new product is first approved or marketed.

Indeed, the realities of drug development mean that drugs are often launched before their full potential has been explored. For example:

- ▶ Parents may want the assurance that a drug is proven safe for use in children and not just adults.



- ▶ Patients and physicians may prefer an improved once-daily drug formulation over the original 3x/day version, or a nasal spray version that provides quicker relief than a tablet.
- ▶ Patients living with rare diseases may benefit from new treatment options, even if that means using an existing drug in a new way.
- ▶ A product approved for one type of cancer may be found to work in other types of cancer as well—or sometimes in other completely different diseases.

From smartphones to heartburn medicine, most innovation occurs through improvements to products over time.

Investing in such changes to existing drugs can make a BIG difference in terms of patient safety, efficacy, and adherence, and thus can be rewarded by the grant of specific patents or regulatory exclusivities.



Third, the U.S. Patent and Trademark Office (PTO) applies the same legal standards to pharmaceutical patents as to other technologies and does not provide patents for trivial modifications to existing inventions. Similarly, the U.S. Food & Drug Administration (FDA) does not grant additional exclusivities for non-substantial changes to existing drugs.



Fourth, if a new patent or regulatory exclusivity is awarded, that new patent or exclusivity applies only to the specific improvement, not the original drug. These additional patents do not in any way extend the original patent. As a result, generics are still able to sell the original version of the drug.

For example: if an innovator improves a drug from a twice-daily to a once-daily dosage form, any patents or exclusivities on the new once-daily form will not block generics from marketing the old twice-daily form. Even new patents or exclusivities on new ways to treat patients with an existing drug often do not block generic sales because of FDA-allowed label “carve outs.”¹⁰

01 Data from Grabowski et al. J. Med. Econ. (2016).
 02 Data from Grabowski et al. J. Med. Econ. (2016).
 03 Titleist Patent Marking, available at <https://www.titleist.com/patents>.
 04 BlackBerry Virtual Patent Marking, available at <https://www.blackberry.com/us/en/legal/blackberry-virtual-patent-marking>.
 05 Nike, Inc. v. Puma North America, Inc., 18-cv-10876 (D. Mass. May 3, 2018), Dkt. 1 (Complaint) at ¶ 26.
 06 Dr. Fresh Oral Health Care – Patents, available at <https://www.drfresh.com/patents/>.
 07 LG Patent, available at <https://www.lg.com/us/patent>.
 08 Bose Patent Information, available at <http://products.bose.com/static/patents/index.html>.
 09 Honeywell Virtual Patent Marking, available at <https://www.honeywellaidc.com/working-with-us/patents>.
 10 See, e.g., 21 U.S.C. § 355(j)(2)(A)(viii).