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How to Obtain Multiple Patent Term Extensions for a Single Product

WRITTEN BY

Kyle A. Dolinsky | N. Nicole Stakleff

This is the second article in our five-part series on PTE.

Everywhere you look, patent term extension (PTE) is described using the "Rule of Ones:" one patent, one product, one PTE. However, the Rule of Ones does not account for the fact that multiple PTEs can be awarded for multiple patents for a single product. Innovators should keep in mind the following when seeking PTEs for their products:

- Multiple PTEs may be awarded based on distinct regulatory review periods for the same product when the approvals occurred on the same day. The PTEs would run concurrently, but may be different lengths depending on the applicable regulatory review period.
- Patent prosecution efforts should be aligned with the multiple PTE strategy.
- Innovators should consider pursuing multiple indications or combination products in parallel, rather than in series, to ensure that eligibility for multiple PTEs is preserved.

PTE allows a patent owner to obtain up to five years of additional term on a patent that covers a drug, biologic or class III medical device.[1] Generally, for a patent to be eligible for PTE, the product must have been subject to a regulatory review period before its commercial marketing, and the product's approval must be the first approval of such a product by the FDA.[2] The PTE statute provides that "in no event shall more than one patent be extended . . . for the same regulatory review period for any product."[3]

Relying on this language, if a product obtains multiple, distinct first approvals on the same day, the U.S. Patent and Trademark Office allows PTE to be awarded for each regulatory review period that was incurred. For instance, if two or more new drug applications (NDAs) were approved on the first same day for the same drug, then that drug could be eligible for multiple PTEs.

Examples of multiple PTEs being awarded include Omnicef® (cefdinir), Lyrica® (pregabalin), Mycamine® (micafungin sodium) and Vimpat® (lacosamide). In these cases, each product was the subject of two separate NDAs with different dosage forms or indications. In each instance, both NDAs were approved on the same day, and the active ingredient had not previously been approved by the FDA. The innovators sought PTE for two different patents covering their drugs — each one relying on the regulatory review period for one of the two NDAs.

In fall 2016, the USPTO awarded three PTEs to three different patents based on the same-day approval of three different NDAs for Nesina® (alogliptin benzoate) and two combination products, Kazano® (alogliptin benzoate and metformin hydrochloride) and Oseni® (alogliptin benzoate and pioglitazone hydrochloride). Alogliptin had never been approved by the FDA before, but metformin and pioglitazone had been.

U.S. Patent No. 8,173,663 was awarded 262 days of PTE for Nesina®; U.S. Patent No. 8,288,539 was awarded 101 days of PTE for Kazano®; and U.S. Patent No. 6,329,404 was awarded five years of PTE for Oseni®. In this case, each product had a different regulatory review period, and each patent was issued on a different day. For each product, the investigational new drug filing dates were different, and the NDA submission dates were different, but each NDA was filed and approved on the same day.

The value of obtaining multiple PTEs on different patents could incentivize innovators to revise their clinical development programs to pursue multiple indications or combination products in parallel, rather than in series. Companies developing a new product should consider reviewing their clinical development plans and exploring approaches with both patent and regulatory counsel to increase the likelihood of obtaining multiple PTEs for their product.

Endnotes

[1] *See* 35 U.S.C. § 156.

[2] *Id.*

[3] 35 U.S.C. § 156(c)(4).

Nicole Stakleff is a partner in Pepper Hamilton's Health Sciences Department, a team of 110 attorneys who collaborate across disciplines to solve complex legal challenges confronting clients throughout the health sciences spectrum. Kyle Dolinsky is an associate in the Health Sciences Department.