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Federal Circuit: Patent Term Extension for Reissued Patents is Calculated Using the Original Patent's Issue Date Where the Original Patent Covers the Drug Product

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The Federal Circuit recently affirmed a district court's holding that patent term extension (PTE) for a reissued patent was properly based on the issue date of the original patent and not that of the reissued patent. The Federal Circuit concluded that, where both the original and reissued patents claimed a drug product under regulatory review, using the issue date of the original patent to calculate PTE comports with both the purpose of the Hatch-Waxman Act and the related statutory context.

Patent owner's original patent issued in 2003 and included claims to a class of compounds that included the drug product. In 2004, patent owner applied for FDA approval. In 2014, while regulatory review was still pending, the patent reissued with the original claims and additional narrower claims, including a claim directed specifically to the drug product. FDA review lasted nearly 12 years, 686 days of which occurred after the patent reissued. After FDA approval in 2015, patent owner applied for and received five years of PTE—the maximum amount permitted under 35 U.S.C. § 156(c)—based on the original patent's issue date.

In 2020, multiple companies filed ANDAs seeking FDA approval of generic versions of the drug product. The ANDAs included Paragraph IV certifications as to the reissue patent. Thereafter, patent owner initiated Hatch-Waxman litigation. During the litigation, the defendants contended that the extension of the reissue patent's term beyond 686 days was invalid under § 282(c). According to the defendants, the plain reading of § 156(c) meant that the PTE should have been calculated from the date of the reissue patent, not the original patent. After a one-day bench trial on the defendants' invalidity challenge under § 282(c), the

district court found that the PTE for the reissue patent was correctly calculated from the original patent issue date, and thus the five-year extension of the reissue patent's patent term was not invalid.

On appeal, the Federal Circuit rejected the defendants' argument that the plain text of § 156(c) meant that "the patent" eligible for PTE could only be the reissue patent. The Federal Circuit began its statutory interpretation analysis by explaining that the text of § 156(c) was ambiguous, thus the specific context and broader context of the Hatch-Waxman Act needed to be considered.

Turning to the purpose of the Hatch-Waxman Act, the Federal Circuit explained that the scheme was set up to compensate a patentee for patent term lost during FDA regulatory review. Thus, the only construction of § 156(c) that comports with this statutory purpose is one that provides PTE to patentees who were unable to benefit from patent protection while waiting for regulatory approval. Furthermore, whether a patentee has an enforceable right in the original patent after obtaining a reissue patent was of no moment because a reissue patent inherits the unexpired term remaining in the original patent. And § 156 is designed to extend the term of the original patent. Thus, where claims in both the original patent and its reissue are directed to a drug product under regulatory review, the Act's purpose would not be served by reducing PTE based solely on a patent holder's decision to seek reissue.

Next, the Federal Circuit explained how its interpretation of § 156(c) was confirmed by related Patent Act provisions. First, § 156(a) provides for the extension of patent terms "from the **original** expiration date of the patent." (emphasis added). Second, under § 154(a)(2), patent term begins on the date "the patent" issues and ends 20 years from the date on which the patent application was filed. Given that a reissued patent inherits the original patent term, the Federal Circuit reasoned that "the patent" must refer to the original patent. The Federal Circuit found further support for its construction from the USPTO's revisions to MPEP § 2766 dealing with PTE.

However, the Federal Circuit explained that § 156(c) would not apply to a patent where the relevant drug product claims in the original patent had been cancelled because such claims are treated as void *ab initio*. The Federal Circuit also noted that, although not present in the case before it, more difficult questions would arise if the original patent did not claim the drug product while the reissued patent did. In that scenario, whether a patentee could

enforce the patent during regulatory review would depend on whether the reissued patent was issued before or after regulatory review.

The Federal Circuit concluded that because the original patent claimed the drug product that was under regulatory review, the reissue patent was entitled to PTE based on the issue date of the original patent.

Practice Tip: A patent owner may desire to seek a reissue patent to obtain claims that are stronger against invalidity challenges. But when the original patent is eligible for PTE, the patent owner should carefully consider whether the reissue patent will still meet the requirements for PTE eligibility. Obtaining a reissue patent will not necessarily shorten the amount of PTE that is available based on the original patent, but the patent owner should ensure that the reissue patent has appropriate claims relating to the approved drug.

Merck Sharp & Dohme B.V. v. Aurobindo Pharma USA, Inc., 130 F.4th 1363 (Fed. Cir. 2025)

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