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Drug Products and Patent Term Extension: Recent Federal Circuit Decision Clarifies Drug Product Definition under Hatch-Waxman Act

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Background: Patent Term Extension

As part of the Hatch-Waxman Act, the term of a patent that claims a new drug product or a method of using the drug product can be extended for up to five years if delays occur during the FDA's regulatory review of the drug product. This extension restores a portion of the patent term that was consumed by the FDA review process, so as to increase the incentive to innovator companies to develop and market products that required extensive FDA review.

Patent term extension is only available for the first commercial marketing or use of the drug product. If the drug product has previously been approved by the FDA, no patent term extension is available for other patents that cover formulations of the drug product or other methods of using the drug product.

The patent owner must apply for patent term extension within 60 days of obtaining FDA approval for the drug. However, the patent owner can rely on the activities of another party, e.g., a licensee, for obtaining patent term extension.

The calculation for patent term extension is based on the time that the innovator drug company spends in taking the drug product through clinical trials and the time it takes the FDA to approve the drug product after submission of a New Drug Application (NDA). In order to obtain the maximum patent term extension, the innovator company must proceed diligently in pursuing FDA approval.

Hatch-Waxman Act and Generic Design-Arounds

In *Pfizer Inc. v. Dr. Reddy's Laboratories, Inc.*, Pfizer had obtained patent term extension by asserting that its U.S. Patent No. 4,572,909 (the '909 patent) covered its drug product Norvasc® or amlodipine besylate. Pfizer's '909 patent claimed a compound having the common name amlodipine and its salts. In obtaining FDA approval, Pfizer submitted clinical data on the besylate and maleate salt forms of amlodipine, and ultimately chose to market the besylate salt form.

Dr. Reddy's Laboratories filed an NDA to market amlodipine maleate and relied on Pfizer's clinical

data that had been submitted to the FDA. Dr. Reddy's Laboratories admitted that the claims of Pfizer's '909 patent covered amlodipine maleate, but asserted that the extension of the '909 patent was limited to the FDA registered drug product, i.e., amlodipine besylate.

Agreeing with Dr. Reddy's Laboratories, the district court dismissed Pfizer's complaint, holding that Dr. Reddy's Laboratories was not infringing the extended term of the '909 patent because the term extension was limited to the first commercial marketing or use of the drug product, which was for amlodipine besylate.

On appeal, the Federal Circuit reversed the district court's judgment of non-infringement. The Federal Circuit analyzed the statute, which stated that patent term extension was for "products," and that "products" were new drugs, including any salt or ester of the active ingredient. The Federal Circuit noted that FDA law and regulations also defined a human drug product as the active ingredient of a new drug, including any salt or ester of the active ingredient. In this case, the accused amlodipine maleate was a salt of Pfizer's amlodipine compound.

The Federal Circuit noted that the Hatch-Waxman Act intended to provide a balance between a patent term extension for innovator drug companies and entry into the market by generic manufacturers. The generic manufacturer could not rely on the innovator drug company's approved uses and clinical data to obtain FDA approval for the same drug and same use, and circumvent the proprietary position granted to the innovator company through its patent term extension.

Conclusion

Under the Hatch-Waxman Act, a patent term extension for a drug product applies to the drug and any salt or ester of the drug. A generic manufacturer cannot avoid an innovator drug company's patent term extension simply by changing the salt form of the innovator company's drug.