Patent Term Extension Under 35 USC 156
By Gene Quinn

The Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act, is responsible for allowing patent owners to extend the patent term due to the need to go through premarket regulatory review. The relevant provisions of Hatch-Waxman sought to eliminate two distortions to the normal "patent term produced by the requirement that certain products must receive premarket regulatory approval." *Eli Lilly & Co. v. Medtronic Inc.,* 496 U.S. 661, 669 (1990).

The first distortion was after the end of the patent term because competitors could not immediately enter the market upon expiration of the patent because they were not allowed to begin testing and other activities necessary to receive FDA approval before patent expiration. This second distortion is addressed in 35 USC 271(e)(1), which provides a safe harbor for otherwise patent infringing conduct that is solely for uses reasonably related to the development and submission of information under a Federal law regulating the manufacture, use, or sale of drugs or veterinary biological products.

The second distortion was that the patent owner loses patent term during the early years of the patent because the product cannot be commercially marketed without regulatory approval from the Food and Drug Administration (FDA). The part of the Act relating to patent term extensions due to delay at Agencies other than the United States Patent and Trademark Office (USPTO) is codified at 35 USC 156, which is designed to create new incentives for research and development of certain products subject to premarket government approval by a regulatory agency.

35 USC 156 enables the owners of patents on certain human drugs, food or color additives, medical devices, animal drugs, and veterinary biological products to restore to the terms of those patents some of the time lost while awaiting premarket government approval from the FDA. The rights derived from extension of the patent term under 35 USC 156(a) are defined by 35 USC 156(b) and are not strictly limited to a claim-by-claim basis, but instead is limited to claims relating to the product, a method of using a product, or a method of manufacturing a product, all of which 35 USC 156(a) says "shall be extended." *See also Genetics Institute LLC v. Novartis Vaccines and Diagnostics Inc.,* 655 F.3d 1291 (Fed. Cir. 2011). Notwithstanding, pursuant to 35 USC 156(b), if the patent claims other products in addition to the approved product, the exclusive patent rights to the additional products expire with the original expiration date of the patent. *See Biogen Int'l GmbH v. Banner Life Scis. LLC,* 956 F.3d 1351 (Fed. Cir. 2020) (holding that the scope of rights during the extended period only included the active ingredient of an approved product, or an ester or salt thereof, and not a deesterified version (metabolite) of the approved product even when the claim recited the deesterified version).

Generally speaking, for a patent owner to take advantage of the available extension under 35 USC 156 an application for the extension of the term of a patent must be submitted by

the owner of record of the patent within the sixty-day period beginning on the date the product received permission for commercial marketing or use. See 35 USC 156(d)(1). Where the regulatory review is of a drug product for which the Secretary of Health and Human Services intends to recommend controls under the Controlled Substances Act, the sixty day period beginning on the "covered date", where the "covered date" is defined as the later of:

- (A) the date an application is approved—
    - (i) under section 351(a)(2)(C) of the Public Health Service Act; or
    - (ii) under section 505(b) or 512(c) of the Federal Food, Drug, and Cosmetic Act;
- (B) the date an application is conditionally approved under section 571(b) of the Federal Food, Drug, and Cosmetic Act;
- (C) the date a request for indexing is granted under section 572(d) of the Federal Food, Drug, and Cosmetic Act; or
- (D) the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act.

Nonstatutory obviousness type double patenting does not invalidate any patent term extension (PTE) granted under 35 U.S.C. 156, if the claims are otherwise valid under its pre-PTE expiration date. See *Novartis AG v. Ezra Ventures LLC,* 909 F.3d 1367 (Fed. Cir. 2018). "For example, if a patent, under its original expiration date without a PTE, should have been (but was not) terminally disclaimed because of obviousness-type double patenting, then this court's obviousness-type double patenting case law would apply, and the patent could be invalidated. However, if a patent, under its pre-PTE expiration date, is valid under all other provisions of law, then it is entitled to the full term of its PTE." *Id*. at 1374, 128 USPQ2d at 1757. The *Novartis* court upheld the validity of a PTE even when the PTE created a potential nonstatutory double patenting issue due to the later date of enforceability of applicable claims of the patent resulting from the PTE finding that the earlier-expired, patentably indistinct patent was "not a double patenting reference" to extended patent. *Id*. at 1375. Specifically, the court held "[b]y applying statutory construction principles, following this court's precedent in [*Merck & Co. v. Hi-Tech Pharmacal Co.,* 482 F.3d 1317, 82 USPQ2d 1203 (Fed. Cir. 2007)], and addressing traditional obviousness-type double patenting principles, we hold that a PTE pursuant to § 156 is valid so long as the extended patent is otherwise valid without the extension." *Id*. Thus, the court declined to allow "a judge-made doctrine" regarding double patenting to "cut off a statutorily-authorized time extension." *Id*. at 1375.

Thus, a patent may be extended under 35 U.S.C. 156, even though it has been terminally disclaimed. A patent term extension under 35 U.S.C. 156 is a limited extension of the patent rights associated with the approved product that is attached onto the original term of the patent. See 35 U.S.C. 156(b). Only one patent may be extended for a regulatory review period for any product, and 35 U.S.C. 156 sets the expiration date of a patent term extension. Although 35 U.S.C. 154(b)(2) (June 8, 1995) precludes a patent from being extended under 35 U.S.C. 154(b) if the patent has been terminally disclaimed due to an

obviousness-type double patenting rejection, there is no such exclusion in 35 U.S.C. 156. Additionally, 35 U.S.C. 154(b)(2)(B)) provides that a patent cannot be adjusted beyond the date set by the disclaimer, but there is no similar provision in 35 U.S.C. 156. Thus, patents may receive a patent term extension under 35 U.S.C. 156 beyond an expiration date set by a terminal disclaimer. See *Merck & Co., Inc. v. Hi-Tech Pharmacal, Co., Inc.,* 482 F.3d 1317 (Fed. Cir. 2007).

To be entitled to patent term extension, 35 USC 156(a)(1) through (5) require that the applicant establish that:

1) the patent has not expired before an application under 35 U.S.C. 156(d) was filed (this may be an application for patent term extension under subsection (d)(1) or an application for interim extension under subsection (d)(5));

2) the patent has never been extended under 35 U.S.C. 156(e)(1);

3) the application for extension is submitted by the owner of record of the patent or its agent to the Office within 60 days of regulatory agency approval of the commercial marketing application and the application includes details relating to the patent, the approved product, and the regulatory review time spent in securing regulatory agency approval;

4) the product has been subject to a regulatory review period within the meaning of 35 U.S.C. 156(g) before its commercial marketing or use;

5) the approval is the first permitted commercial marketing or use of the product (35 U.S.C. 156(a)(5)(A)), except in the case of human drug products manufactured using recombinant DNA technology where the provisions of 35 U.S.C. 156(a)(5)(B) apply, or in the case of a new animal drug or a veterinary biological product where the provisions of 35 U.S.C. 156(a)(5)(C) apply.

35 U.S.C. 156(c)(4) also requires that no other patent term has been extended for the same regulatory review period for the product.

The USPTO initially determines whether the application is formally complete and whether the patent is eligible for extension. The statute requires the Director of the USPTO to notify the Secretary of Agriculture or the Secretary of Health and Human Services of the submission of an application for extension of patent term which complies with 35 USC 156 within sixty days and to submit to the Secretary a copy of the application. Not later than thirty days after receipt of the application from the Director, the Secretary will determine the length of the applicable regulatory review period and notify the Director of the determination. If the Director determines that the patent is eligible for extension, the Director calculates the length of extension for which the patent is eligible under the appropriate statutory provision and issues an appropriate Certificate of Extension.