



PATENT TERM EXTENSION FOR BIOTECHNOLOGY PATENTS

BIOTECHNOLOGY AND LIFE SCIENCES PRACTICE TEAM

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THE PATENTS AND PRODUCTS ELIGIBLE FOR EXTENSION UNDER 35 U.S.C. § 156

The Drug Price Competition and Patent Term Restoration Act, also referred to as the Hatch-Waxman Act, was enacted in 1984. As part of the legislative package, Congress provided for extension of the patent term for patents disclosing new drugs for human use, new medical devices, new food or color additives, new drugs for animal use and new veterinary biological products, in certain cases to compensate for patent term lost in obtaining regulatory approval. The Act restores a portion of the patent term during which the patentee is unable to sell or market a product while awaiting government approval, such as the Food and Drug Administration's ("FDA") review of a prescription drug.

Under 35 U.S.C. § 156, the term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended from the original expiration date of the patent if five requirements are satisfied. These requirements are: (1) the term of the patent has not expired; (2) the term of the patent has never been extended; (3) an application for extension is submitted by the owner of record of the patent or its agent; (4) the product has been subject to a regulatory review period before its commercial marketing or use; and (5) the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the law under which such regulatory review period occurred. Importantly, the fifth requirement has an exception, which allows a patent claiming a process for making an approved product using primarily recombinant DNA technology to be extended under § 156 even if the product has already received commercial marketing approval. Further, except as provided by the fifth requirement, the petition for extension of the term of a patent must be filed within sixty days of the marketing approval.

The Act specifically addresses the loss of patent term which occurs before a product is marketed or sold to the public. For example, because a patent has a twenty year term extending from the application filing date, and assuming that patent examination took four years and the FDA approval process took an additional seven years, the effective term of commercial exploitation would otherwise only be nine years. The application of § 156 allows the term of a U.S. patent to be extended for the length of time approximately equal to the length of time the FDA approval process delayed commercialization or use, up to a maximum of five years. 35 U.S.C. § 156, therefore, mitigates the loss of patent term caused by FDA delay in approving the new product.

However, the extension of patent term under § 156 is subject to a number of limitations: (1) only one extension is available for the patent, even though the patent may claim multiple FDA approved products; (2) the Applicant is penalized for failing to act with due diligence during the FDA approval process; (3) the extension is the period between the date the patent was granted and the date of

PILLSBURY WINTHROP LLP

Client Alert

July 1, 2004

marketing approval, with the proviso that the sum of this period and the patent term remaining at the date of approval must not exceed 14 years; (4) only one patent that claims the approved product may be extended, even though multiple patents may claim the product (e.g., a first patent claims the product and a second patent claims a method of using or making the product); and (5) the maximum extension available is five years, even where the FDA delay is greater than five years.

Another limitation under § 156 is that the patent term extension only applies to products or processes subject to regulatory review. Thus, if a patent claims an approved product or process as well as other unapproved products or processes, it is only the FDA approved product or process that is extended under § 156. This creates the unusual situation where claims directed to an approved product or process would have a different patent term than claims directed to unapproved products or process within the same patent.

Similarly, having two commercial embodiments claimed in the same patent, each of which has been subject to FDA approval, has the consequence of forcing the applicant to choose which drug they want for the patent term extension, since an extension cannot be obtained for both. On the other hand, it is possible to obtain patent term extension by filing two patents directed at two drugs that are within the same genus. For example, a first patent claiming an FDA approved drug extended under § 156 would not appear to prevent extension of a second patent claiming an FDA approved second drug that is within the same genus as the first FDA approved drug. As a consequence, continuation and divisional patents based upon the same originally filed patent application claiming different FDA approved drug may each be entitled to extension under § 156. Accordingly, the ability to obtain § 156 extensions for patents encourages the filing of separate patent applications each claiming a different drug, which the patent holder believes has the most commercial potential.

COURT INTERPRETATIONS

▪ Patent Must Claim Either The Active Ingredient Or Its Use

Courts have narrowly interpreted the language of § 156. In particular, the meaning of the term “claims” was at issue in *Hoechst-Roussel Pharmaceuticals Inc., v. Lehman*,¹ where the Federal Circuit reviewed the district court’s affirmation of the United States Patent and Trademark Office’s (“USPTO”) denial of the plaintiff’s application for extension under § 156. Hoechst argued that its patent claiming a metabolite, 1-hydroxy-tacrine, of an FDA approved drug, tacrine-hydrochloride, was entitled to patent term extension. Hoechst’s patent claims the compound 1-hydroxy-tacrine and a method of treating a patient in need of memory enhancement by administering an effective amount of 1-hydroxy-tacrine. Tacrine-hydrochloride, after ingestion, metabolizes into 1-hydroxy-tacrine and other compounds. The USPTO, however, denied the extension on the grounds that: (1) Hoechst was not a proper applicant because it was not involved in the FDA approval of tacrine-hydrochloride, and (2) the patent did not claim the FDA approved tacrine-hydrochloride or a method of using the product.

First, Warner-Lambert Company, which is not a party to this case, submitted a new drug application to the FDA for approval to market the drug COGNEX® to treat Alzheimer’s disease. The active

¹ 109 F.3d 756 (Fed. Cir. 1997).

PILLSBURY WINTHROP LLP

Client Alert

July 1, 2004

ingredient in COGNEX® is tacrine-hydrochloride. The FDA approved Warner-Lambert's drug. Hoechst sued Warner-Lambert for infringement of its patent which discloses and claims the compound 1-hydroxy-tacrine and a method of treating a patient in need of memory enhancement using 1-hydroxy-tacrine. Since, tacrine-hydrochloride, after ingestion, metabolizes into 1-hydroxy-tacrine and other compounds, Warner-Lambert admitted that tacrine-hydrochloride infringed certain claims of Hoechst's patent. Thus, the court entered a consent judgment of infringement.

While the suit was pending, Hoechst filed an application for extension of the term of its patent, based on the regulatory review of Warner-Lambert's COGNEX®. Hoechst rationalized that if the claims were infringed by the FDA approved product, then the infringed claims were within the meaning of the term "claims" as used in § 156 and were eligible for term extension. However, because it was Warner-Lambert whose FDA application was approved, not Hoechst, the Commissioner decided Hoechst was not the proper applicant for patent term extension. The district court affirmed.

Additionally, in applying the plain meaning to the Act's use of the term "claims", the USPTO argued that the patent claimed 1-hydroxy-tacrine and a method of treating a patient with that compound. The patent did not "claim" tacrine-hydrochloride, which was the product that, after injection, metabolized into 1-hydroxy-tacrine, or the method of using tacrine-hydrochloride. Thus, the Commissioner decided that Hoechst had not claimed either the active ingredient that received FDA approval or its use. Instead, Hoechst claimed a chemically distinct compound and the method of using that compound.

On appeal, Hoechst argued that Congress intended the meaning of "claims" to include anything that infringes the claims, but the Court found that the legislative history was "not an extraordinary showing of contrary intentions" to the plain meaning of the term. The Court concluded that because Hoechst's patent did not claim tacrine-hydrochloride, which had received regulatory approval, or its use, the patent was ineligible for extension under § 156. Thus, in view of *Hoechst*, patents that do not "claim" the FDA approved product are ineligible for extension under § 156.

▪ Patent Term Extension Applies To The Approved New Drug And Its Salts Or Esters

Merck & Co. Inc. v. Teva Pharm. USA, Inc.,² was a case where the Court considered the invalidity of the patent term extension. The Federal Circuit affirmed the district court's ruling that Teva Pharmaceuticals USA, Inc. and Zenith Goldline Pharmaceuticals, Inc., (collectively "Teva") not only infringed a patent, owned by Merck & Co., but also that the patent was properly entitled to term extension. The patent at issue had one claim to a product that had been given the common name alendronic acid. Merck, however, marketed the alendronate salt under the brand name Fosamax. Teva was sued by Merck after it filed an Abbreviated New Drug Application ("ANDA") to sell the generic version of Fosamax. In its defense, Teva argued that: (1) Merck was not entitled to a patent term extension because the approved product is not alendronic acid, but the monosodium salt, and (2) Teva did not literally infringe Merck's patent because the patent claim was directed to the alendronic acid and Teva's ANDA was for the monosodium salt. The Federal Circuit disagreed with Teva's theories.

² 347 F.3d 1367 (Fed. Cir. 2003).

PILLSBURY WINTHROP LLP

Client Alert

July 1, 2004

In considering whether Merck was entitled to the patent term extension, the Federal Circuit gave the “appropriate deference” to the USPTO’s determination as to which patents were entitled to term extensions. Accordingly, the court construed the claims to include the usage of the monosodium salt. Support for the claim construction was found throughout the specification, such that the specification described the acid active agent as encompassing the acid and its salt forms. Hence, the Federal Circuit concluded that Merck was appropriately allotted the term extension and that the scope of the claims included the salt forms. As a consequence, Teva was found guilty of infringement.

In *Pfizer Inc. v. Dr. Reddy’s Laboratories, Ltd.*,³ the Federal Circuit similarly interpreted the breadth of a patent approved for patent term extension to include not only the new drug, but also, any salts or esters of the active ingredient that was approved by regulatory review. In this case, Pfizer’s patent covered Norvasc®, an anti-hypertensive, anti-ischemic drug product whose active ingredient is amlodipine. The specification described clinical data of amlodipine besylate and amlodipine maleate. Pfizer selected the besylate salt for regulatory review. The FDA approved the besylate salt. After regulatory review, Pfizer obtained patent term extension of 1252 days, from February 25, 2003 to July 21, 2006.

Dr. Reddy’s sought use of amlodipine maleate. Dr. Reddy’s argued that the term extension only applied to amlodipine besylate. The district court agreed with Dr. Reddy’s and dismissed Pfizer’s complaint. On appeal by Pfizer, the Federal Circuit disagreed with the lower court’s decision and reversed it, finding that “the district court misconstrued the statute...the Act by its terms extended the term of the patent for the registered uses of the drug product including its salt esters.”

In so holding, the Federal Circuit, discussed the definition of the term “drug product” under 35 U.S.C. § 156(f). The term is defined as “the active ingredient of a new drug ... including any salt or ester of the active ingredient.” The court considered that the FDA had ruled that the term “active ingredient” as used in the phrase “active ingredient including any salt or ester of the active ingredient” to mean “active moiety.” *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50,338, 50,358 (F.D.A. Oct. 3, 1994). Further, the FDA defines “active moiety” as “the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . responsible for the physiological or pharmacological action of the drug substance.” 21 C.F.R. § 314.108(a). Accordingly, the Federal Circuit interpreted 35 U.S.C. § 156(f) to extend patent term for the new drug, as well as any salts or esters of the active ingredient.

▪ In A Combination Product, One Active Ingredient Must Be New To The Marketplace

On March 24, 2004, the Federal Circuit upheld, in *The Arnold Partnership v. Godici*,⁴ the USPTO’s denial of patent term extension for a patent application claiming a combination of hydrocodone (or a pharmaceutically acceptable acid addition salt thereof) and ibuprofen (or a pharmaceutically acceptable acid addition salt thereof) as well as methods of treating pain with this composition. Both hydrocodone and ibuprofen had previously been marketed separately. However, the combination of

³ 2004 U.S. App. Lexis 3784 (Fed. Cir. 2004).

⁴ Fed. Cir. March 24, 2004. District court, *Arnold Partnership v. Rogan*, 246 F.Supp.2d 460 (E.D.Va. 2003), did not err in upholding the USPTO’s interpretation of section 156,

PILLSBURY WINTHROP LLP

Client Alert

July 1, 2004

hydrocodone and ibuprofen had never been marketed. Even though, the FDA required a New Drug Application (NDA) before clearing the combination of hydrocodone and ibuprofen (“Vicoprofen”), the USPTO did not consider the combination drug the first commercial marketing of the product. Thus, the USPTO ruled that Vicoprofen did not comply with the fifth condition under § 156(a), i.e., the “first commercial marketing” requirement .

The plaintiff argued that the meaning of the term “product” means a single active ingredient, even where multiple active ingredients are present. As a consequence, because the combination of hydrocodone and ibuprofen is the “product” within the meaning of § 156(a)(5)(A), and hydrocodone and ibuprofen as a combination drug had not been previously marketed, the patent claiming hydrocodone and ibuprofen was therefore eligible for extension under § 156. The district court agreed with the USPTO’s decision and held that patent term extension under § 156 may not be based on a combination of active ingredients where the individual ingredients have already been separately approved for marketing. The Federal Circuit affirmed.

The USPTO’s decision was based upon a policy in place since 1989 that, in order for a combination of active ingredients to be eligible for extension, at least one of the active ingredients must not have been previously approved for commercial marketing or use. For this reason, the USPTO determined that the patent was not eligible for patent term extension to compensate for the delay caused by regulatory review.

The Federal Circuit decision was based on a closer look at the statutory language of “a drug product.” In particular, subsection (f) defines “a drug product” as “the active ingredient of a new drug . . . product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.” The subsection uses the disjunctive to show that the drug product may consist of either a single ingredient or an active ingredient in combination with another active ingredient. Accordingly, the Federal Circuit reasoned that the statute places a combination drug product having two active ingredients in the same category as a drug with a single active ingredient. To extend the term of a patent claiming a composition comprising multiple active ingredients, one ingredient must not have been previously marketed. As a result, at least one of the claimed active ingredients must be new to the marketplace as a drug product.

LEGISLATIVE HISTORY OF 35 U.S.C. § 156

A review of the congressional record surrounding § 156 indicates that most courts have interpreted the provision consistent with congressional intent. For example, there are frequent statements in the congressional record that a patent can only be extended one time and, furthermore, that a patent may not be extended if another patent that claims the approved product or process has been granted an extension under § 156. *See House Report Part I*, p. 3, 7-39 and 75-76; *House Report Part 2*, p. 1-8 and 21-22, reproduced in Allan M. Fox and Allan R. Bennett, *The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984*, at 109-110 and 112-113 (FDLI 1987).

One amendment of significance was to allow the patent holder to decide which patent could obtain the extension. The legislation limiting the extension to only the first issued patent of a series of patents was eliminated out of concern that a first patent claiming a genus would issue, and a second

PILLSBURY WINTHROP LLP

Client Alert

July 1, 2004

later patent claiming the FDA approved drug would issue, but would be ineligible for a term extension under § 156. Interestingly, when Congress eliminated language that would have limited the extension to the first issued patent, language that would have prevented the extension for later filed patents based upon patents disclosing the drug was also deleted. In other words, a first patent claiming an FDA approved first drug that is extended under § 156 would have prevented any later filed patent from obtaining an extension for anything the first patent disclosed. Thus, as it stands, any later filed patent related to a first patent claiming an FDA approved first drug is not prevented from obtaining a § 156 extension for a different FDA approved drug, even if the drug were disclosed in the first patent.

As to the meaning of the term “product,” the congressional record appears to be consistent with the PTO and court interpretations that it means the active ingredient, salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. *House Report Part I*, at pp. 43, reproduced in Fox and Bennett at pp. 126.

One glaring exception is *Hoechst*, in which congressional intent appears to be contrary to the majority opinion. For example, when discussing why the term “claims” was selected, the House Report states that “because it is the term used in the patent law to describe the invention which the patent owner or its assignee may prevent others from making, using or selling during the seventeen year term of the patent. For instance, in the case of a product patent which ‘claims’ a broad genus of compounds, the patent owner could prevent others from making, using or selling any compound which is a species of that genus.” *House Report Part I*, at pp. 37-39, reproduced in Fox and Bennett at pp. 109. This statement suggests that Congress understood that by using the term “claims”, the meaning of the term was to include not only what is expressly claimed but also, what infringes. This language indicates a congressional intent more consistent with Justice Newman’s concurring opinion in *Hoechst*, which would permit a patent holder to obtain an extension under § 156 if the FDA approved product would infringe a claim of that patent, provided that all other conditions for extension have been met.

THE CALCULATION

The maximum patent term extension available to an applicant is five years, but the patent term remaining at the date of approval must not exceed 14 years. Generally, the extension available is calculated by adding one-half the time in the testing phase — investigatory new drug (IND) — , and all of the time in the approval phase — the new drug application (NDA) —, and subtracting from this figure any time the Applicant was not diligent during the approval process. A sample calculation form is attached to this client alert. Please consult with your patent counsel for additional information on calculating the patent term extension.

THE IMPLICATIONS OF PATENT-TERM EXTENSION FOR BIOTECH COMPANIES

The delays and costs associated with new pharmaceutical developments and regulatory testing necessitate an inquiry into eligibility of a patent term extension. Under § 156, full patent term protection for FDA approved drugs may be achieved to protect the interests of the patentee and the biotech companies investing time and effort in the FDA approval process.

PILLSBURY WINTHROP LLP

Client Alert

July 1, 2004

FURTHER INFORMATION

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PILLSBURY WINTHROP LLP

Client Alert

July 1, 2004

CALCULATION OF LENGTH OF PATENT TERM EXTENSION FOR A HUMAN DRUG PRODUCT			
1.	Enter the number of days for the testing phase as defined in 37 CFR 1.775(c)(1)		
2.	Enter the number of days for the approval phase as defined in 37 CFR 1.775(c)(2)		
3.	Add line 1 and line 2 and enter the total here		
4.	Enter the number of days of the period of line 2 which occurred prior to the issue date of the patent		
5.	Enter the number of days the period of line 2 during which the applicant failed to act with due diligence as defined in 37 CFR 1.775(d)(1)(ii)		
6.	Add line 4 and line 5 and enter the total here		
7.	Subtract line 6 from line 3 and enter the difference here (if less than zero enter 0)		
8.	Enter the number of days of the period of line 1 which occurred prior to the issue date of the patent		
9.	Enter the number of days of the period of line 1 during which the applicant failed to act with due diligence as defined in 37 CFR 1.775(d)(1)(ii)		
10.	Add line 8 and line 9 and enter the total here		
11.	Subtract line 10 from line 7 and enter the difference here		
12.	Enter the number of days from line 1		
13.	Enter the number of days from line 10		
14.	Subtract line 13 from line 12 and enter the difference here (if less than zero enter 0)		
15.	Multiply line 14 by 0.5 (one half) and enter the amount here		
16.	Subtract line 15 from line 11 and enter the difference here (if less than zero enter 0)		
17.	Enter the original expiration date of the patent		
18.	Enter the expiration date of the patent if extended by the number of days on line 16		
19.	Enter the date of the FDA (Food and Drug Administration) final approval		
20.	Limitation set forth in 37 CFR 1.775(d)(3)		
21.	Add the number of years on line 20 to the date on line 19 and enter the revised date here		
22.	Enter the earlier date appearing on line 18 or line 21		
23.	Enter the original expiration date of the patent (from line 17)		
24.	Check one of the following three boxes and enter the listed time period here		
	<input type="checkbox"/>	The patent issued after 24/9/84	5 Years
	<input type="checkbox"/>	The patent issued prior to 24/9/84 and no request for exemption as defined in 37 CFR 1.775(d)(6)(i) was filed prior to 24/9/84	5 Years
	<input type="checkbox"/>	The patent issued prior to 24/9/84 and an exemption as defined in 37 CFR 1.775(d)(6)(ii) was filed prior to 24/9/84	2 Years
25.	Add the number of years on line 24 to the date on line 23 and enter the revised date here		
26.	Enter the earlier date appearing on line 22 or line 25		
27.	Enter the original expiration date of the patent (from line 17)		
28.	Enter the number of days by which line 26 and line 27 differ here This is the length of patent term extension		

INFORMATION OBTAINED FROM THE U.S. PATENT AND TRADEMARK OFFICE

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