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Patent Term Extensions Extend Revenues

Even with recent steps taken by the FDA to "fast track" the new drug application and approval process, the period between application and approval remains lengthy. As a result, patent holders may be deprived of the full benefit of their patent. To remedy this loss of patent protection, many countries have adopted patent term extension laws allowing patent holders to recover the vital time lost to the regulatory review process. Even one additional day of patent protection can mean over a million dollars in revenues on a blockbuster drug product. This article describes the patent term extension process in the United States, Europe and Japan, summarizes two recent judicial decisions interpreting the laws and suggests strategies for drafting patent claims and licenses to take advantage of patent term extensions.

United States. In 1984 Congress enacted the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), codified at 35 U.S.C. §156. The Hatch-Waxman Act counteracts the lengthy regulatory approval process for new drug products by increasing the life of the patent for a term equal to the regulatory review period, which is defined as one-half of the period commencing on the effective date of the Investigational New Drug Application ("IND") to the filing of the New Drug Application ("NDA"), plus the time from the submission of the NDA to the date of FDA approval of the NDA. Extensions are limited to 5 years, and no product shall have more than 14 years marketing exclusivity after it receives NDA approval.

Term extensions are available under the Hatch-Waxman Act for patented drug products and methods of using or manufacturing the products. The application for term extension must be filed within 60 days of receipt of marketing approval, and prior to expiration of the patent. In addition, the patent owner (or the owner's agent) filing for extension must have participated in the regulatory review process, which should be properly documented.

The Hatch-Waxman Act only extends the term of the patent claims that are directly covered by the FDA's authorization; other claims in the patent are not subject to extension. The Hatch-Waxman Act also limits the number of patents eligible for term extension to one extension per product and one extension per patent. Thus, if a patent contains claims relevant to more than one product, extension is available for only one of those products.

Europe. In Europe, the effect of a patent term extension is obtained under a Supplementary Protection Certificate ("SPC"). Unlike the Hatch-Waxman Act, which extends the life of particular claims under a patent, an SPC is a separate right extending the marketing exclusivity for a particular medicinal product or the methods of using or manufacturing that product. To obtain an SPC for a product, such product must be covered by a "basic patent." The holder of the basic patent must apply for an SPC in each EU country that issued a patent covering the product, within 6 months of obtaining the first marketing authorization for the product in each such country, or if the marketing authorisation comes before grant, within 6 months of the grant of the patent. In contrast to the U.S. system which allows only one extension per product, if a product is protected by a number of "basic patents," each of those patents may be designated for an SPC, so long as the respective applications are filed before the first SPC is granted. In addition, because an SPC is "product-" and

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not "patent" specific, more than one SPC may be issued based on the same basic patent, so long as each product has a different active ingredient and a separate marketing authorisation.

SPCs continue for a period equal to the time elapsed between the filing of the patent application and the grant of the first EU marketing authorisation, less five years. Accordingly, the maximum combined marketing exclusivity in Europe is 15 years, one year longer than the U.S. allows; however, similar to the Hatch-Waxman Act, the maximum term extension provided under an SPC is limited to five years.

Japan. Japanese Patent Law also provides that the term of a patent may be extended by a period not to exceed 5 years to compensate for time lost to regulatory review. Eligibility requirements for extension include (i) that the regulatory approval delay exceed 2 years, (ii) the patent term must not have expired before the date of application for the extension, and (iii) the application for extension must be filed within 3 months of the marketing approval and at least 6 months before expiration of the patent. In addition, patent term extension requests must be filed by the patentee, and drug approval must have been received by the patentee, an exclusive third-party licensee, or a registered non-exclusive licensee. In contrast to the United States, Japan like Europe, allows the same patent to be extended multiple times, provided that each extension is applicable to a different product. Japan also allows multiple patents covering a single product to be extended so long as the multiple extensions are regarded by the patent office as necessary.

Drafting Claims. To maximize the benefits of patent term extensions, patent attorneys need to consider the application of the patent term extension laws during the drafting process. In drafting patent applications, claims of varying scope should be presented, ranging from broad generic compositions and broad methods, to narrow claims on what may become an approved product (e.g., active ingredients). In the U.S., patent drafters should consider claiming different active ingredients in separate patents, because a patent term can be extended only once and any patent extension is limited to the first of such active ingredients approved by the regulatory authorities. Likewise, patent drafters should try to include all claims that will apply to a single product, such as an active ingredient and its method of use, in the same patent application if permitted by the patent examiner so that all claims applicable to a single product are eligible for extension.

License Drafting. When a patent holder licenses its patent to another party to enable such party to develop a product, the license should include provisions addressing the issue of patent extensions. SPCs are separate intellectual property rights and need to be included in the definition of patent term extension, and the obligation to pay royalties should be extended concurrent with any patent term extensions. The parties should also develop a procedure for obtaining extensions, establishing which party will have the obligation to file extension applications, and where and when such applications should be filed. Furthermore, in the likely event that not all claims applicable to an approved product are contained within the same patent, the license should require that the parties agree upon a strategy to maximize patent protection for the product, whether that means choosing to extend the claims with the broadest protection, or the claims that expire at the latest date. W&D

Recent Cases Clarifying the Law.

Recent judicial decisions in the United States and Europe help clarify this area of law where patent principles, business interests and public health concerns compete. Two particularly relevant cases are described below:

In Pfizer Inc., v. Dr. Reddy's Laboratories, Ltd., (U.S., December 2002) a federal district court determined that a patent term extension granted under Hatch-Waxman is not applicable to all claims in such patent; instead, only the claims directly related to the approved product are eligible for term extension. The court found that the patent term extension granted to Pfizer for a patent claiming the molecule amlodipine and its derivative salts (including amlodipine besylate and amlodipine maleate), was limited to the active ingredient in Pfizer's approved drug product. The FDA approved Dr. Reddy's Laboratories' NDA to market amlodipine maleate. In dismissing Pfizer's patent infringement suit, the court held that the patent term extension applied only to the amlodipine besylate salt, the active ingredient in Pfizer's FDA-approved product, and not other compounds claimed under the extended patent.

In *Takeda Chemical Industries v. Comptroller General of the Patent Office,* (U.K. April 2003), the Court found that a combination product is ineligible for an SPC unless each product in the combination is specifically identified with the basic patent designated by its holder for the SPC. In this case, the UK Patent Office rejected Takeda's application for an SPC for combination drug therapy for the use of the compound lansoprazole in combination with certain antibiotics because Takeda only had patents covering one compound, lansoprazole. Takeda appealed the decision, but the Court agreed with the Patent Office holding that the combination product had to be protected by a basic patent in force; in this case, the Takeda patents covered only the lansoprazole element of the combination product, and accordingly no SPC was granted.