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PATENT TERM RESTORATION

INTRODUCTION

"Patent Term Restoration" in the United States is no longer merely an "idea whose time has come" but a fact of life, a reality.

"The Drug Price Competition and Patent Term Restoration Act of 1984" (Public Law 98-417), enacted on September 24, 1984, restores part of the patent protection lost by new drugs, antibiotic drugs, human biological products, medical devices, and food and color additives, as a result of FDA premarket testing and approval requirements (Title II) and establishes the procedures under which the Food and Drug Administration (FDA) may approve applications for generic versions of pioneer new drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Title I).

In recent years, several laws -- the Toxic Substances Control Act; the Federal Insecticide, Fungicide and Rodenticide Act; and the Food, Drug and Cosmetic Act -- have been enacted that require premarket testing and government review of industrial chemicals, agrichemicals, pharmaceuticals, and food additives. As a result of the government-mandated testing and review requirements, the average effective patent life of a pharmaceutical is about seven years and an agrichemical is 10 to 12 years instead of 17 years.

The idea of compensating patent owners for at least part of the lost patent life gained momentum in 1980. Legislation to grant up to seven additional years on a patent because of the premarket testing and agency review requirements was seriously considered in 1981-82, but it never passed both houses of Congress. During 1983-84, the 98th Congress, legislation granting patent extension of up to five years was given to patents on human pharmaceuticals. Unfortunately, legislation allowing the extension of patents on agrichemicals and industrial chemicals stalled and died in late 1984 at the end of the 98th Congress.

The two arguments most often given in support of patent term restoration relate to equity and to incentives for research investment. Members of Congress readily

respond to the argument that it is basically inequitable to grant a full 17 years of exclusive use to the inventor of a new skate key, for example, while the inventor of a pesticide that will help farmers produce food for a growing world population receives only ten to twelve years. In addition, Congress has granted patent extension to human pharmaceuticals, and they should grant similar protection to patents on agrichemicals which also must undergo government-mandated premarket testing and review.

Both former President Jimmy Carter's Advisory Committee on Industrial Innovation and President Reagan's Commission on Industrial Competitiveness recommended passage of patent term restoration legislation to provide adequate incentives for continued investment in research and development.

PUBLIC LAW 98-417

This law provides that the term of a patent eligible for extension can be extended for a period of time equal to the amount of time taken for regulatory review of clinical testing which occurred after the patent had issued. However, the period of extension may not exceed five years. In addition, the period of extension, when added to the patent life left after regulatory approval of

the product, may not exceed 14 years. For products either being tested or awaiting approval at the time of enactment of the new law, the extension may not exceed two years. The period of extension would be reduced if, during any period of regulatory review, the applicant did not act with due diligence in pursuing the regulatory review process.

The rights derived from any patent extension extend only to the particular product under development, not to all the compounds of the involved patent or claim, and not to totally distinct types of uses for a claimed product. An extended patent on a drug, while properly covering all drug uses, would not preclude a competitor from selling the compounds after its normal patent life, for example as a stabilizer.

Any patent which claims a "product", or a method of using such a "product", or a method of manufacturing such a "product", is entitled to having its term extended.

The term "product" means (1) a human drug product or (2) any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug and Cosmetic Act. The term "human drug product" means the active ingredient of a new drug, antibiotic drug, or human

biological product (as these terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

To obtain a patent term extension, the patent owner would have to submit an application to the Commissioner of Patents and Trademarks, along with a $750 filing fee. The patented product which is the subject of such application must have received permission for commercial marketing or use and (a) the application for extension of term must be filed within the 60-day period beginning on the date the product first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred, or (b) in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension must be submitted within the 60-day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent.

The term of a patent may not be extended if the patent has expired before the submission of the

application for extension. There must be no multiple patent extensions for one product even if a second patent represents, in addition to a new invention, a new regulatory review period of clinical testing.

APPLICATION FOR RESTORATION

More specifically, the formal requirements for an application to the USPTO for patent term restoration are set forth in the Guidelines published in the Official Gazette on October 9, 1984 (1047 O.G. 16-20) and comprise the following:

(1) a complete identification of the approved product

(2) a complete identification of the Federal statue under which the regulatory review occurred;

(3) an identification of the date on which the product received permission for commercial marketing or use occurred;

(4) a statement that the application is being submitted within the sixty day period;

(5) a complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, and the date of issue;

(6) a copy of the patent for which an extension is being sought in single column form;

(7) a copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent;

(8) a statement that the patent claims the approved product or a method of using or manufacturing the approved product, and a showing thereof;

(9) the relevant dates and information pursuant to 35 USC 156(g) in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review period;

(10) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities;

(11) a statement that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including now the length of extension was determined;

(12) a statement that applicable acknowledges a duty to disclose any information which is material to any determinations to be made relative to the application for extension;

(13) the prescribed fee of $750 and

(14) an oath or declaration which specifically identifies the application papers and the patent for which an extension is sought and avers that the person signing the oath or declaration;

(a) has reviewed and understands the contents of the application

(b) believes the patent is subject to extension;

(c) believes an extension of the length claimed is fully justified under 35 USC 156; and

(d) believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent.

LENGTH OF EXTENSION

Two aspects of the preparation of an application for extension of term of a patent which merits further discussion are the calculation of the "Regulatory Review Period" by the FDA and the determination of the length of extension to be claimed.

The legislation divides the Regulatory Review Period into two separate periods, which subsequently have been denominated by the FDA as the "Testing Period" and the Application Period". The Regulatory Review Period is the

sum of the Testing Period and the Application Period, regardless of when the patent issued. The question of due diligence during the Regulatory Review Period will be addressed by the FDA only when a petition which the FDA deems meritorious is submitted.

Therefore, the relevant dates and information required to determine the Regulatory Review Period are the dates that each of the Testing Period and Application Period began and ended.

In the case of human drugs, the Testing Period begins when the IND becomes effective which is normally 30 days after it is submitted or when a clinical hold is removed. The Testing Period begins when the NDA is initially submitted to the FDA and accepted as complete for review by the FDA. The date of the approval letter ends the Application Period.

After the Regulatory Review Period has been determined by the FDA, it is the responsibility of the PTO to determine the maximum amount of patent term restoration. Since the Applicant is required to provide a statement as to the length of the extension claimed, the preliminary calculations are done by the Applicant and contained in the application.

The formula for this calculation, simply stated, involves adding one half of the length of the Testing Period to the entire length of the Application Period, after subtracting any time that may have occurred during the Regulatory Review Period before the patent issued. However, the resulting period of time is subject to either a two-year or a five-year maximum and a fourteen-year cap.

In a stepwise fashion, the following calculations can be made:

(1) The length of the Testing Period;

(2) The length of the Application Period;

(3) The length of the Regulation Review Period after the patent issued.

(4) The determination of whether a two-year or five-year maximum applies and the appropriate reduction, if necessary; and

(5) The determination of whether the fourteen year cap is applicable and if so, the appropriate reduction in the length of the extension.

The resultant period of time should be claimed as the length of extension sought.

REVERSAL OF BOLAR DECISION

The new law also overrules the CAFC decision of Roche Products Inc. v. Bolar Pharmaceutical Co., Inc. 122 USPQ 937 (CAFC 1984) by amending 35 USC 271 to exempt from infringement the making, using, or selling of patented drugs solely to satisfy FDA testing regulations. Therefore, the new law establishes that experimentation by a non-patentee of a drug patented by another, during the term of the patent, in order for the non-patentee to prepare for commercial activity which is to begin after the patent expires, is not patent infringement.

AGRICULTURAL PATENT REFORM BILL

Animal drugs and pesticides are not included in the new law but on May 7th, Senator Charles McC. Mathias introduced legislation (S.1093) that would restore to the term of a patent covering certain agricultural and chemical products the period of time, up to five years, lost as a result of complying with federal pre-marketing requirements.

S.1093 would extend the term of a patent on certain agricultural and chemical products in order to compensate

for the time lost because of pre-market regulatory review requirements. This process consumes, on average, five to seven years.

The term "product" is defined by the bill to include: (1) any new animal drug or animal antibiotic subject to regulation under the Federal Food, Drug, and Cosmetic Act; (2) any veterinary biological product subject to regulation under the Virus-Serum-Toxin Act; (3) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act; and (4) any chemical substance or mixture subject to regulation under the Toxic Substancxes Control Act.

Some of the bill's major provisions are set forth below:

1. The time of the patent extension shall be equal to the time spent testing the product and the time spent reviewing the data by EPA; this combined period is known as the regulatory review period. However, in no case may an extension exceed five years.

2. The starting time of the recovery period shall be the initiation of a major health or environmental effects test which is defined as a test lasting six months or longer.

3. No product which is already being marketed at the time the legislation is enacted into law will be entitled to patent extension. No extension shall be granted to an expired patent.

4. If a product is being tested or undergoing EPA review when the bill is enacted into law, the patent may not be extended for more than three years.

5. Only one patent on a product may be extended for a regulatory review period, and the extension shall apply only to the uses of the patented product for which it underwent testing and agency review.

CONCLUSION

Patent term "restoration" in given areas is fine and good. What is really needed is a general extension of the patent term across the board to at least 25 years.*

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* See my attached unpublished paper "Are Seventeen Years of Patent Protection Enough?"