
Chapter 6

The Mechanics of Patent-Term Extension

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INTRODUCTION

Throughout this report, patent-term extension has been discussed as a concept, but the specifics of its form have not been reviewed. The effects of patent-term extension will, however, vary depending on the technical details of the extension.

By extending the period in which a patentee may exclude others from making, using, or selling his invention, patent-term extension provides potential rewards to the patentee. However, it also delays use of the innovative technology by others. Thus, to assess the effects of patent-term extension on innovation, *one* must compare the value of the extended protection for the patentee with the reduced use of the technology by others after the original patent term expires. This comparison can only be made in terms of the type of extension that is granted.

The effects will vary depending on whether the entire patent right is extended or whether the focus of the extension is narrowed to a portion of the invention claimed in the patent. For example, a chemical patent may claim several new chemicals, only one of which is marketed as a drug. If the full patent right were provided during the extension, the patentee could exclude others from making, using, or selling any of the patented chemicals for any purpose. Under this circumstance, those aspects of the patented

technology that were not subjected to the Food and Drug Administration's (FDA) premarketing review would have patent protection for more than 17 years. The rights protected during the extension could be modified in a fashion that would still provide meaningful incentives for the patentee but yet allow others to use the patented technology for some purposes during the extension.

As seen in chapter 5, claims can be made for chemicals, compositions of known chemicals, processes, or methods-for-use but not all classes of patents are considered to have equal value. The relative value of each of the classes can be further affected by modifications of the patent rights during the extension. These modifications and their implications *on* the classes of claims are discussed in the following sections.

Modifications could be directed at the scope of claims during the extension, the products, processes, and uses against which the patent could be enforced during the extension, and the remedies available to the patentee for infringement of the patent during the extension.

Two other aspects of patent-term extension will significantly influence its effects: the duration of the extension, and the obligations of the patentee during the extension.

LIMITATIONS IN SCOPE AND ENFORCEMENT

The most important factors affecting the balance between the degree of protection provided to the patentee and the extent to which the patented technology can be used by others during the extension are those relating to limitations in scope and limitations in enforcement. Although these factors are described separately, they are interactive.

Scope: A patent claim defines the breadth of the invention for which the patent rights are sought. The claim may contain many possible embodiments of the invention, and the full scope of the claim would include all of the embodiments. A limitation in the scope of the claim would result in the claim being narrowed during the extension. For example, a chemical

claim is directed to chemicals A, B, and C in its full scope. If the scope were limited during the extension to only chemical A, the making, using, or selling of chemicals B and C for any purpose would fall outside the narrowed scope of the claim and would not be an infringement.

Enforceability: A patent is enforceable against an infringement of the invention defined by the claim. In the above example, during the original term of the chemical patent, the patentee can enforce the patent against anyone in the United States who makes, uses, or sells any of chemicals A, B, or C, regardless of how the chemical is made or used. During the extension, the enforceability of the claim might be limited by conditions not expressed in the claim. For example, the patentee might only be permitted to enforce the patent against anyone who used or sold the chemical for a particular purpose. Thus, if the enforceability of the claim were limited to chemicals A, B, and C, as used for treating headaches, the claim would not be enforceable against someone who made or sold any of the chemicals for gasoline additives.

Limitations in Scope

If the full scope of the claim could be enforced during the extension, the effects of the extension on the patentee's rights and the availability of the technology for use by others would be those described in chapter 5. If, however, the scope were limited during the extension, the effects would vary depending on the way in which the scope was limited and the type of claim involved.

The scope of claim could be limited in three ways:

- **Method S.1**—The extension might be provided only for those aspects of the patent claims that involve the specific active chemical approved by FDA.
- **Method S.2**—The focus of the claim might be narrowed during the extension by restricting the parameters (e.g., temperature range, dosage amount, or type of chemical) recited in the claim to the specific value existing in the FDA approved product, process, or method-for-use.

- **Method S.3**—The extension might be provided only for the specific chemical (in the case of chemical claims), composition (in the case of composition claims), the specific process (in the case of process claims), or method-for-use (in the case of method-for-use claims) approved by FDA regardless of whether a parameter for each product, process, or method-for-use condition is recited in the claims.

Examples of these methods are provided in the discussion of the various types of claims. These examples are provided to help explain both the concepts involved in these methods and the distinctions between them. As will be seen in the following sections, meaningful patent protection could result if the full scope of the claim is enforceable during the extension or if the scope is restricted, according to method S.1, to the active chemical approved by FDA. Methods S.2 and S.3, however, provide little protection for composition, process, and method-for-use claims.

Chemical Claims: For chemical claims, there is no difference in the amount of protection provided by any of these methods. Since the aspect of the claimed invention involved in the specific FDA approval is a chemical, all of the methods would restrict the claim during the extensions to the specific chemical contained in the FDA approved product.

During the extension any other chemical claimed in the patent could be freely made, used, or sold by others. For example, even a minor modification of the chemical would create a different chemical and take it outside the scope of the extended patent. During the extended period, therefore, the patentee could face direct competition from chemicals covered by his claims during the original patent term. However, the competitor would have to undergo the expense of conducting safety and efficacy tests for FDA approval of the modified chemical. Moreover, the modified chemical would not be chemically and therapeutically equivalent to the existing drug and could not be generically substituted for the patented drug. The developer of the modified product would, therefore, have to establish a market for the drug.

Because of the nonpatent barriers that supplement the patent protection, these methods provide the patentee with moderate protection.

Although it is possible that the modified chemical might have enhanced therapeutic value, the therapeutic value in most cases would be similar to that of the patented drug. Thus, considerable effort would be spent by competitors to secure FDA approval but few social benefits would accrue. The innovator could attempt to broaden the scope by securing FDA approval (and patent-term extensions) for other chemicals within the original scope of the claim, but, such efforts, while blocking competition, would be costly and would provide few benefits to society.

Composition Claims: For composition claims, the three different methods would have different effects on the amount of protection provided to the patentee and the availability of the technology for use by others.

Assume that a composition claim recites: "A therapeutic composition for treating headaches in humans comprising a unit dosage amount of chemical A or B in an inert carrier" and that the product approved by FDA consists of **0.4** milligrams of chemical A and 3 grams of sodium stearate as a binder.

If method S.1 were used to limit the scope to chemicals approved by FDA, the claim would apply to compositions containing chemical A and any carrier. Thus, the scope of the claim would be limited more by chemical than by composition, and the claim would cover many compositions for which FDA approval was not sought. The scope of the claim would still be broad and the value of the claim to the patentee would be similar to the value of a chemical claim.

If method S.2 were used, to restrict the scope to the specific values for the recited parameters present in the FDA approved composition, the claim would be limited to compositions containing chemical A and sodium stearate. The claim would still cover many compositions for which FDA approval was not sought. The value of the claim would be limited to the patentee since many possible inert carriers exist; by selecting a

different, but equivalent carrier, the claim could be avoided. The modifications to avoid infringement would, however, necessitate FDA approval.

If method S.3 were used and claims were restricted to the precise embodiment approved by FDA, the claim would, in our example, be limited to compositions containing **0.4** milligrams of chemical A and 3 grams of sodium stearate. Because the claim covers only one composition it could be easily circumvented.

Process Claims: FDA, in approving a drug, also approves the processes by which it is made. The aspects of the claimed invention involved in the specific FDA approval are, therefore, the process conditions.

For example, the process claim recites: "A process for making chemical A or A' by admixing chemical X or X' and chemical Y and heating the mixture to between 500 and 800 C in the presence of a dehydrating catalyst." The process used to make chemical A, which was approved by FDA, involves very specific conditions including amounts of reactants and purification procedures.

If extensions were based on method S.1 and the scope of claims were limited to chemicals approved by FDA, in our example the claim would be limited to a process for making chemical A using the specified reactants, a reaction temperature between 500 and 80° C, and any dehydrating catalyst. The process could be used by anyone to make chemical A'. Many processes for making chemical A other than the one specifically involved in the FDA approval would be covered by the claim.

If method S.2 were used and the scope of claims during the extension were narrowed to the specific values of parameters in the FDA approved invention, the claim would be limited to processes for making chemical A using the specified reactants, a specific temperature, and a specific catalyst. If method S.3 were used, the claim would be limited to the precise process involved in the FDA approval including process limitations not specifically recited in the claim, e.g., the amounts of the reactants and the procedure for purifying chemical A.

Under methods S.2 and S.3, the patent could be easily avoided by minor and insignificant process modifications and the patentee would have disclosed specific process information to the public so that the scope of the claim would be known. Methods S.2 and S.3 would not provide meaningful patent protection.

Method-for-Use Claims: The method used for extending patent terms can have a significant effect on the value of method-for-use claims.

Assume that a method-for-use claim recites: "A method for relieving pain in a human comprising internally administering a therapeutically effective amount of chemical A or B" and that the FDA approval is for orally administering 10 to 20 milligrams of chemical A three times a day to relieve the pain of headaches in adults.

Under method S1, the claim would be limited to any internal administration of chemical A to relieve pain. The patentee could exercise his rights against another who used or sold chemical A for the treatment of any pain, e.g., arthritis, even though the FDA approval was only for the treatment of headaches.

Under method S.2, the claim would be limited to any oral administration of 10 to 20 milligrams of chemical A to relieve the pain of headaches. Under method S.3, the claim would be limited to the specific use of orally administering 10 to 20 milligrams of chemical A three times a day to relieve the pain of headaches in adults.

Under methods S.2 and S.3, others could use chemical A for relieving the pain of arthritis. Both of these methods present problems of enforcement since doctors could prescribe and consumers use chemical A (produced by another as an arthritis pain reliever) for treating headaches; the only remedy available to the patentee would be to sue each of the infringers individually.

Limitations in Enforcement

If no limitations were placed on enforcement, the patent could be enforced against any product, process, or use that falls within the scope of

the claim regardless of the purposes for which it would be used. Thus the public would have no right to use any of the patented technology during the extension. There are, however, methods for limiting enforcement of actions during the extensions:

- Method E1: During the extension the patent could be enforced only against a pharmaceutical product, process, or use that requires FDA premarketing approval.
- Method E.2: During the extension the patent could be enforced only against one who uses the claimed invention for the same therapy that was specified in the patentee's drug application and for the therapy (termed "specific therapy approved") for which FDA approval was granted.

These methods are illustrated in relation to the following example: the patentee has a chemical claim on chemical A and obtains FDA approval for treating headaches with chemical A.

Under method E1, the patent could be enforced against anyone making, using, or selling chemical A as a drug, (e.g., sale of the drug for treating high blood pressure would be prohibited) but not against anyone making, using, or selling chemical A for a nondrug use, even though the nondrug use might be regulated. Thus, one could sell the chemical as an herbicide. Method E.1 therefore enables the public to use the patented technology during the extension for other than drug uses. Such use would not result in competition for the innovator's drug.

Under method E.2, the patent could only be enforced against anyone making, using, or selling chemical A for treating headaches. Method E.2 could significantly affect the patentee's incentives but could provide the public with a greater right to use the patented technology during the extension,

From the standpoint of the patentee, method E.2 presents a disadvantage since the patent would be enforceable only when the drug is used for the specific therapy approved. A competitor could obtain FDA approval and manufacture and sell the identical drug for a different therapy; yet the doctor could prescribe or the con-

sumer could use the competitor's drug for the specific therapy approved. As with method-for-use patents discussed in chapter 5, the patentee may not have an effective mechanism to enforce his patent. His only remedy would be to sue each of the prescribers or users for patent infringement.

From the standpoint of promoting pharmaceutical innovation, method E.2 (limiting enforcement to the specific therapy approved) could be beneficial for developing new therapies for existing drugs. A competitor would have an incentive to develop another pharmaceutical use for the drug so that he could market it. The patentee would also have an incentive to develop other pharmaceutical uses so that those uses would be covered during the extension. While some uses developed may provide significant improvements in health care, others may not.

Interaction Between Limitations of Scope and Limitations of Enforcement

By combining scope limitations with enforcement limitations, one can achieve a desirable balance between meaningful patent protection for the patentee and public use of the patented technology during the extension. Three combinations of the methods discussed appear to be most attractive from the standpoint of balancing these sometimes conflicting objectives. Each combination strikes a different balance.

Combination A:

- Limitation in scope: Method S. I—Claims restricted to the chemical approved by FDA.
- Limitation in enforcement: Method E.1 — Enforcement only against FDA approved product, process, or method-for-use.

In combination A the scope of the claim would be limited to the chemical approved by FDA, and the patent could be enforced only against products, processes, or methods-for-use which were subject to FDA approval. Of the three combinations, this one would provide the most protection to the patentee.

Combination A would have the following effects:

- the patented technology could be used for all but pharmaceutical purposes;
- others could produce minor variations of the chemical and use the technology for drugs;
- others could not develop the approved chemical for new FDA uses; and
- the patentee could enforce the patent against anyone who marketed an identical drug regardless of the drug therapy for which it was prescribed or used.

Combination B:

Ž No Imitation in scope.

- Limitation in enforcement: Method E.2— Enforcement limited to specific therapy approved.

With combination B, the claim would be interpreted to its full scope; however, the patent could only be enforced against anyone who made, sold, or used the patented product, process, or method-for-use for the specific therapy approved. This combination differs from combination A in that the claim would be broader with respect to the active chemicals covered, but the patented technology could be used for other drug therapies.

Combination B would have the following effects:

- the patented technology could be developed for all uses other than the specific therapy approved by FDA; and
- enforcement would not be practicable against an identical drug developed for a different therapy but prescribed or used for the patentee's therapy.

Combination C:

- Limitation in scope: Method S.1—Claims restricted to chemical approved by FDA.
- Limitation in enforcement: Method E.2— Enforcement limited to specific therapy approved.

Under combination C, the scope of the claim would be linked to the chemical or chemical and use approved by FDA, and the patent could only be enforced against the sale or use of the patented product, process, or method-for-use

for the specific therapy approved. Of the three combinations, this combination would provide the least protection to the patentee.

Combination C would have the following effects:

- others could make, use, and sell minor variations of the chemical for uses identical to the specific therapy approved;

- others could develop the patented technology for all uses other than the specific therapy approved; and
- enforcement would not be practicable against an identical drug developed for a different therapy but prescribed or used for the patentee's therapy.

LIMITATIONS IN REMEDIES

In the original patent term a patentee can secure an injunction against an infringer and obtain damages for the infringement. Proposals have been made to limit the remedies available to the patentee during the extension period. The most restrictive proposal would not permit the patentee to exclude others from making, using, or selling the patented drug but would require him to license the invention for a reasonable fee (compulsory licensing).

If the objective of extending the patent term is to increase the potential for returns to the innovating firm, compulsory licensing would probably not accomplish that objective. The benefits of a reasonable royalty are likely to be less than the benefits received by the patentee through the sales of products. Moreover, the determination of a reasonable royalty can be difficult, expensive, and time-consuming. Burdens would be placed on both the administrators of the law and on the firms contesting

the royalty. Most significantly, compulsory licensing would create an uncertainty which would not be resolved until a request for a license was made and granted. For these reasons, compulsory licensing could detract from any incentive for pharmaceutical innovation provided by patent-term extension.

There are, however, intermediate grounds. For example, compulsory licensing could be required only if the firm were not satisfying the needs of the public or if the licensing were essential for national security (e.g., to assure more than one source of supply in the event of a catastrophe). Such intermediate grounds presently exist to protect national interests. Title 28, section 1498 of the U.S. Code, provides that the United States can use or manufacture, or have used and have manufactured for it, a patented invention without the patentee's permission. The patentee however, is entitled to reasonable compensation for such use and manufacture.

THE DURATION OF THE EXTENSION

Several proposals have been made for establishing the duration of the extension.

- the duration could be a period which enables the innovator to obtain adequate remuneration for the invention, and would be decided on a case-by-case basis (proposal D.1);
- the duration could be a predetermined and uniform period (proposal D.2);

- the duration could be the period between the date on which the innovator was prepared to commercialize the invention and the date on which marketing approval was obtained (proposal D.3); or
- the duration could be a period corresponding to at least a part of the time consumed in the regulatory review process (proposal D.4).

Each of these proposals could be modified in such a way that the extension would be terminated if the drug were not being sold by the innovator firm or if the patented technology (e.g., in the instance of a patented process) were no longer being used for the drug.

Proposal D.1: Adequate remuneration.

This method would pose significant administrative problems but because very few new drugs are marketed (between 40 and 100 new drug applications (NDAs) are approved per year), the problems would be small in number. More significantly, the determination of adequate remuneration would be subject to controversy. The extension is most meaningful to the research-intensive companies as it applies to drugs that have been most profitable during the original patent term. Unless the extension included these drugs, the economic benefits from pharmaceutical innovation provided by patent-term extension would be significantly reduced.

Because this method would not provide the public with notice that the patent was being extended until the expiration date of the original patent term was approaching, potential competitors might not initiate steps for manufacturing and marketing the drug until they knew that no extension would be granted. Thus, if the administrative proceedings were lengthy, a de facto extension might result.

Proposal D.2: Predetermined and uniform period.

Extending the patent term for a predetermined period, e.g., 7 years, might result in inequities, with some drugs being protected for more than 17 years. There would be no direct correlation between the regulatory approval time and the patent life. This method, however, would be easy to administer.

Proposal D.3: Marketing delay compensation.

Determining the delay between the time when a firm was ready to market a product and the time the product was approved by FDA would be difficult and the determination would be subject to dispute. Making these determinations would be an administrative burden. Moreover,

firms would be encouraged to prematurely proceed with manufacturing plans in order to increase the extension which could be obtained. If the firm timed its manufacturing plans according to the progress of the drug through FDA, the measured delay might be unduly brief.

Proposal D.4: Time consumed in the regulatory review process.

This proposal, which makes the duration of the extension dependent on the time consumed by the regulatory proceedings, overcomes some of the difficulties and inequities of the other three proposals. Because the dates that premarketing approval procedures begin and end are known, this method would not impose a great administrative burden.

Basing the period of extension on the regulatory review period could compensate the patentee for time he would have spent developing and testing the drug even if FDA did not exist. The likelihood of this occurring would depend on when the period eligible for compensation begins. If the objective of patent-term extension is to encourage pharmaceutical innovation, the issue of whether the patentee receives excess compensation may not be of prime importance.

If proposal D.4 were adopted, the innovators might delay the testing needed to secure premarketing approval. But, such dilatory tactics would also delay the marketing and would therefore be disadvantageous to innovators. If, however, the new drug would compete with an existing drug of the innovator firm, dilatory tactics might be used. But such tactics are discouraged by the courts. If a patentee has purposefully delayed steps needed for FDA approval, the court may refuse to enforce the patent, but proving purposeful delay can be quite expensive and time-consuming.

The effects of this proposal would depend on when the period eligible for compensation begins. In general, the earlier in the regulatory process that the clock starts ticking for determining the duration of the extension, the longer and more economically meaningful the patent-term extension will be. There are a number of dates at which the clock could start.

The period could begin on the date that the NDA was filed with FDA. The period between NDA filing and final approval is frequently about 2 to 3 years. This amount of time might be insufficient to provide significant additional incentives for pharmaceutical innovation. A predetermined period of time could, however, be added to the extension. In some instances, adding a predetermined time would more than compensate for time lost in the regulatory review process.

The period eligible for compensation might instead begin on the date that the first clinical trials in the United States were initiated. The time between the initiation of clinical trials and the approval of the NDA for new chemical entities is frequently 5 to 8 years. Beginning the clock at the first clinical trials could result in significantly extended patent terms.

Alternatively, the period eligible for compensation could begin on the date on which the investigational new drug (IND) application is filed with FDA. The filing date of an IND is easy to determine and the filing of an IND is a precondition to the initiation of clinical trials in the United States. The IND could be filed long before clinical trials began.

Another proposal would begin the eligibility period when substantial preclinical animal tests (e.g., tests of longer than 6 months) were

started. These tests are frequently initiated prior to the filing of an IND.

Maximum Extension Period

A maximum period of extension has been proposed to eliminate extensions of long duration and to discourage innovator firms from delaying the premarketing approval process to obtain later expiration dates on extensions.

The effects of the extension will depend on the length of the extension. If the maximum period is too short, the potential for incentives for pharmaceutical innovation may be too small to be meaningful. If the maximum period is too long, the social costs of innovation may outweigh its benefits.

The maximum extension could simply be a specific number of years with no qualifications. Proposals have been made, however, that would prevent the extension from going beyond a fixed time from the filing of the first patent application.

This constraint could act as a disincentive for delaying proceedings in the Patent Office. If the date of the filing of the first patent application were selected as the starting point, the patentee would receive no benefit from filing continuation or divisional applications to delay the issuance of the patent application.

OTHER CONSIDERATIONS

There are several other aspects of patent-term extension that must be addressed. Should extensions be granted to marketed drugs that are ordered off the market for further testing? Should patent extensions be granted in cases involving alternative uses of drugs, since alternative uses also must be approved by FDA?

With respect to the first question, extending a patent to compensate for the period when the product is ordered off the market could pose difficulties. If an extension were granted only when a Federal regulatory agency ordered a withdrawal, the innovator firm might be reluctant to voluntarily withdraw the product until such an

order was issued. In any event, drugs are withdrawn from the market infrequently.

With respect to the second question, drugs frequently possess efficacy in more than one therapeutic area. The ability to extend the enforceability of the patent to other therapeutic uses that the patentee has developed might promote innovation. If the enforceability of the patent were limited during the extension to the specific therapy approved, the additional extension would not have any effect on the length of the extension for the first use. If the enforceability were not so limited, providing an extension for another therapy would also extend the patent

for the first therapy, and the patentee could therefore increase the effective patent term for the first therapeutic use.

The Number of Patents Extended per Drug

It is possible that more than one patent may provide protection to a drug. The issue dates of the patents may differ, thereby allowing the patent protection provided by a later-issued patent to extend beyond the expiration of the first patent. Patent-term extension could be restricted to only one patent per drug or could apply to each patent covering the drug. Depending on the method used for determining the length of the extension, permitting more than one patent to be extended could result in extensions that expired at different times. If the method for determining the extension corresponded to the effective patent term lost due to premarketing review, no patent could have its term extended beyond 17 years.

The Obligations Incurred by the Patentee

In the normal operation of the patent system, a patent is granted and, in return, the public

receives a disclosure of the invention and a description of its best mode. The patentee incurs no further obligations (other than maintenance fees) during the patent term.

Proposals have been made to impose additional obligations on the patentee in return for the extended patent period:

1. after the extension the patentee could be required to provide potential competitors with available data (results from clinical and toxicity testing) needed for securing FDA approval for generically equivalent drugs;
2. after the extension the patentee could be required to relinquish all rights to the trade name;
3. after the extension the patentee could be required to allow others to use the size, color, and shape of the drug that is coming off patent;
4. during the extension maximum prices for the drug could be mandated; and
5. patentees could be required to use a portion of the revenues derived during the extension for research and development.