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# PATENT TERM EXTENSION: AN OVERREACHING SOLUTION TO A NONEXISTENT PROBLEM

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**T**he proponents of extended life for drug patents argue that the “effective patent life” of pharmaceutical composition and use patents has been cut in half due to the additional time now required to comply with government safety and efficacy regulations prior to commercial marketing. They define “effective patent life” as the period of actual commercial exploitation of a patent monopoly and claim that it has been reduced from seventeen to 7.5 years. Since the proposed legislation (S. 255; H.R. 1937) would extend patent life only for a maximum of seven years, they contend that it would provide less than the full return of time to which pharmaceutical innovators are entitled as a matter of equity.

To those who lack a basic understanding of our complex patent system, this argument seems simple and logical, and for that reason it has attracted broad support. In reality, the arguments which have been made in support of patent extension have no reasonable foundation in fact or law; and the extension legislation undermines fundamental principles on which the entire patent system is based for, at least, the following reasons:

## **1) Effective patent life.**

The term “effective patent life” is the creation of those who are promoting patent extension legislation and has no counterpart in patent law or the fundamental philosophy on which the patent system is based. The notion that the seventeen-year patent grant carries with it any guarantee that the patent owner will enjoy seventeen years of commercial exploitation of the patented invention is contrary to that philosophy, as well as to the requirements which must be met to obtain a patent, particularly in the pharmaceutical field.

## 2) Government regulation.

Government regulation is only one of many factors which have an effect on the length of a commercial monopoly, and it is less significant than many others, all of which are largely under the discretion and control of the patent owner. These factors include when the patent application is filed in relation to the state of development of the invention; how long the patent application remains pending in the United States Patent and Trademark Office before a patent is granted; the scope of the patent in relation to the commercial product which it seeks to dominate; the number and type of patents which may be available to cover different aspects of the commercial development; the time at which clinical investigations are commenced in relation to the patent application and issue date; and the pace of commercial development in terms of the time, effort, and money invested to reach the commercial stage. The statistics which have been put forth in support of the proposition that "effective patent life" is now 7.5 years do not tell us which of the foregoing factors actually played a significant role in the net result and make the inaccurate assumption that regulatory delay is the exclusive cause.

## 3) Equity concept.

The extension legislation in its present form goes far beyond the "equity" concept on which it is being promoted. The application of equitable principles would dictate that any patent extension would be no greater, in either duration or scope, than the delay actually caused by the government. In fact, the legislation would extend the life of a product patent claim for all therapeutic end uses and not merely the end use which is the subject of regulatory review. It would also make it possible to obtain extended patent protection for compositions which were not specifically known or disclosed in the patent, but were covered by broad hypothetical composition claims. This approach will serve to discourage improvements and innovations by third parties which the patent system was designed and intended to encourage. Further, the true length of government-caused delay is, in fact, no greater than the difference between the date on which a reasonably prudent businessman, subject to product liability claims, would commercially release a product and the date on which the government commercially releases the product by approval of a new drug application (NDA). The Senate-passed bill would grant an extension from a time commencing long prior to the first clinical tests in human subjects, thereby rewarding rather than discouraging delay.

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**Effective Patent Life Is a Nonexistent Concept**

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The patent system was established to promote the progress of science and the useful arts by encouraging inventors to make early disclosure of their inventions to the public in the belief that such disclosures would prevent wasteful duplication of research. This would stimulate further inventions and improvements which would make the earlier disclosures on which they were based obsolete. The system was primarily designed to benefit society and not to create private fortunes for the owners of patents, although it has always been recognized that some reward is essential as an inducement for the invention disclosure.<sup>1</sup>

The inducement provided by the patent law is not a positive grant of the right to commercial exploitation of the invention for the life of a patent, but rather a negative grant, namely, the right to exclude others from making, using, or selling the invention for a period of seventeen years. Whether or not the patentee derives a commercial benefit from that exclusion is a matter which is totally divorced from the patent system and depends upon a multitude of other factors including the commercial practicality of the invention disclosed in the patent, the state of its development, the existence of a market and, of course, the existence of other laws which determine whether a particular device can be used or sold and, if so, under what conditions.

Until the present controversy concerning patent extension, no one connected with the patent system believed or argued that the grant of a patent created a positive right to exploitation for a fixed period of time. Indeed, the fundamental rules pertaining to what must be disclosed in a patent make it clear that patents are designed to disclose ideas and not necessarily to support the ultimate commercial manifestation of those ideas.

If the basic purpose of the patent system was to convey to the inventor a positive grant of a fixed period of commercial exploitation, a logical requirement of the patent system would be a full disclosure of the commercial embodiment of the invention, and the patent claims would precisely define that commercial monopoly. In contrast, one of the fundamental rules of our patent system prohibits the grant of a patent if the invention was publicly disclosed or commercially used for more than one year prior to the date on which a patent application is filed.<sup>2</sup> This rule exists because the patent grant is a reward solely for the early disclosure of the invention to the public and not a reward for either its discovery or for an investment in its commercial development and exploitation. If society would eventually obtain the benefit of the invention through its public disclosure or commercial use, no reward to the inventor is necessary and none is given by the patent system.

Under the United States patent system, with certain difficult-to-prove

exceptions, the patent is granted to the first inventor who actually discloses the invention in a patent application and not to the first person who may have actually made the discovery.<sup>3</sup> It is self-evident that this system encourages the filing of patent applications at the idea stage, rather than at a stage when they are ready for commercial exploitation.

A patent may only be obtained if the invention described in the patent is useful, but the standard for determining utility is not a commercial standard. Indeed, after the passage of the 1962 amendments to the Food and Drug Law which required pharmaceutical manufacturers to establish safety and efficacy prior to marketing therapeutic compositions, the United States Patent and Trademark Office took the position that patents covering therapeutic compositions could not be granted without proof that the claimed compositions met the Food and Drug Administration (FDA) standards with respect to safety. This position was overruled by the highest patent court, the Court of Customs and Patent Appeals, on the ground that an invention could be “useful” in the sense of the patent law, even though it might not be commercially saleable under other laws.<sup>4</sup> In so ruling, the court adopted the argument that one fundamental purpose of the patent grant, recognized by the *Report of the President’s Commission on the Patent System*, was to stimulate the investment of additional capital needed for the further development and marketing of the invention. Having successfully taken the position that patents should be granted on therapeutic compositions which are clearly not in commercial form at the time the patent is granted as a stimulus to investment, it is completely disingenuous for the pharmaceutical companies to now urge that the grant of a patent entitles them to seventeen years of commercial exploitation.

Clearly all of the foregoing fundamental principles on which the patent system is based completely undermine the argument that the concept of “effective patent life” exists, or that, in any event, it is intended to be equal to the seventeen-year life of a patent. Pharmaceutical companies are not, as they allege, the victims of any inequity caused by the granting of a monopoly by one government agency (the Patent Office) and an alleged interference with the exploitation of that monopoly by a different agency (the FDA). Rather, they seek to redefine the concepts on which the patent system is based by urging that the patent grant is a guaranteed seventeen-year monopoly.

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### Factors Affecting Commercial Patent Life

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Given the basic principles of the patent system, what are the factors which actually affect so-called “effective patent life”, or more accurately, the length of the commercial monopoly on a therapeutic composition?

How can it be that it is demonstrably far longer than seventeen years in some instances and significantly shorter in others? Regulatory review is not the exclusive answer to these questions. There are a multitude of patent and economic factors, *largely under the discretion and control of the patent owner*, which can dramatically affect the answer.

The patent application filing date, patent issue date, and scope of a patent application are factors which may have an important effect on the length and scope of a commercial monopoly. This can be readily demonstrated by considering the following patent rules and practices:

- ♦ The patent law contains no requirement that a patentable idea be at any particular stage of development before a patent application may be filed. Obviously, if no patent application is filed until the invention is reasonably well along in the development process, it is likely that the inventor will enjoy a longer period of commercial exploitation. By waiting, the inventor runs a risk that others will file earlier patent applications on the same invention with the possible result that all patent protection will be denied and, worse yet, that someone else will possess a monopoly which will prevent the commercial practice of the invention. Not surprisingly, many patent applications are filed long before it is known if the inventions are commercially practical, solely as a defensive measure and without regard to any possible impact on the life of any subsequent commercial monopoly.
- ♦ It is perfectly permissible to file a patent application on a concept which has never been tested or which is far broader than the limited concept which has actually been tested. In pharmaceutical composition cases, for example, it is quite common to define the invention by a broad hypothetical chemical formula which encompasses hundreds or thousands of possible compounds having certain structural similarities, even though, at the time the original patent application is filed, only a small handful of compounds have actually been made and tested.
- ♦ The seventeen-year patent monopoly runs from the date on which the patent is actually granted, after it is examined by the United States Patent and Trademark Office, and does not run from the filing date of the patent application. How long a patent application remains pending in the Patent Office is highly variable and, to a significant extent, can be controlled by the inventor. It is entirely permissible to keep a patent application pending for a long time by abandoning the original patent application in favor of so-called continuation or continuation-in-part applications which supplement or expand upon the original invention disclosure, and which are based on work carried out by the inventor subsequent to the original application filing date. The use of this practice is widespread and has been common in pharmaceutical industry patents.
- ♦ By law, each patent must be limited to a single invention and, in many

instances, the method of making a product or the method of using a product. Although initially disclosed in a single patent application which also discloses the product, these methods are required to be set forth in separate, so-called divisional applications. This practice leads to a multiplicity of patent applications, all of which travel through separate tracks in the Patent Office and may issue at separate times. Indeed, it is common practice to refrain from filing divisional patent applications covering processes or methods of use until just prior to the issuance of the product patent. Thus, the expiration of a single patent cannot be automatically equated with the loss of commercial monopoly because the methods of making and using that product, which are disclosed in the expired patent, are also the subject of separately issued patents having later expiration dates. In addition, commercially crucial composition variations or methods may also be set forth in later filed continuation-in-part applications, or independent patent applications as research proceeds towards a more precise definition of the nature of the commercial products, methods, and uses.

The permissible and discretionary manipulation of the foregoing patent rules can sometimes lengthen and sometimes shorten the actual commercial monopoly. For example, the early filing of a patent application covering an extremely broad class of chemical compounds based on preliminary research with only a handful of compounds, makes it more likely that the date of initial commercial exploitation of a product may not occur until long after the patent issues. Indeed, the specific structure of the actual compound to be marketed may not even be known either at the time the patent application is filed or the time when the patent issues, despite the fact that the patent contains broad claims which cover it! One leading advocate of the patent extension concept has described this as "a situation of common occurrence" in pharmaceutical patents.<sup>5</sup> Obviously, any reduction in "effective patent life" which flows from the fact that the true invention was not made until after the patent was granted cannot be blamed on regulatory delay.<sup>6</sup>

There is, of course, a definite benefit to the patent owner which flows from the filing of early speculative patent applications, even though there is a potential loss in the length of the actual commercial monopoly. The industry rapidly becomes aware that broad patent protection is being sought by a company in a particular area of chemistry, both as a result of publication in scientific journals and the publication of corresponding foreign patent applications within eighteen months of the U.S. filing date. These publications serve to discourage competitive research, thereby preserving that area for one company on a long-term basis. Any marginal loss suffered as a result of shortened commercial life for the first broad patent application can, and often is, offset by a long

and complicated series of additional patent applications covering the methods of use, methods of production, further composition variations, varying dosage forms, and the like. It becomes a relatively simple matter in the absence of direct competition to obsolete the original commercial compounds as they near their patent expiration dates and promote the use of a variant covered by a new generation of patents.

An alternative and commonly used strategy involves the early filing of a broad speculative patent application which is eventually abandoned in favor of one or more continuation or continuation-in part applications as additional research begins to focus on the preferred compositions. The use of this procedure not only strengthens and broadens the scope of protection, but also postpones the issue date of the patent, thereby extending the period of commercial monopoly.

**T**he possible variations are limitless, and some examples may serve to illustrate at least some of the foregoing principles. In the case of Valium, the original patent application was filed in December 1959 and disclosed the specific chemical entity Diazepam which is sold under the Valium trademark. But the patent application also contained broad claims to a large class of compounds having a structure similar to Valium, although many of those compounds had never actually been produced or tested. In May 1960, the Patent Examiner indicated that he was willing to grant a patent which specifically covered Valium, but was unwilling to grant the claims to the broader class of compounds because of the lack of specific disclosure to support them. Rather than accept a patent which covered the specific commercial compound, Roche abandoned the original patent application in favor of a series of continuation-in-part applications which were intended to supplement the original disclosure and support the broader claims. The procedures relating to these matters consumed approximately eight years, and no patent covering Valium issued in the United States until 1968. Since Valium had actually been discovered before the initial patent application was filed, the clinical research occurred wholly within the period when the patent application was pending and NDA approval to market Valium was granted in 1963. Accordingly, Roche will have enjoyed twenty-two years of commercial monopoly by the time its patent expires in 1985. The laws of the United States are far more generous in this regard than the laws of other countries. In most industrial nations, the patent monopoly expires twenty years after the patent application is filed, so that any procedural delays in obtaining issuance of the patent cannot benefit the patentee. It is for that reason that the Valium patent expired in much of the rest of the world in 1980.

The history of Keflex, generically known as cephalexin monohydrate,

demonstrates a different set of circumstances affecting the length of a commercial monopoly, and undermines the assertion that the expiration of a single patent eliminates the commercial monopoly. The initial patent application describing a large new class of cephalosporin antibiotic compositions was filed by Lilly in 1962, but only the method of making those products was actually claimed in the initial patent application. The first patent application actually claiming those products was not filed until 1966, shortly before the method patent was granted. That product patent application contained a hypothetical chemical formula; which was broad enough to cover the compound known as cephalixin, although that compound had not yet been discovered. Cephalixin monohydrate, the commercial form of Keflex, was not actually discovered until a later date, while the patent application which broadly covered (but did not disclose) cephalixin was still pending in the Patent Office. Lilly then filed a new patent application claiming cephalixin monohydrate as a separate invention. The broad patent covering cephalixin was granted in 1970, and the specific patent covering cephalixin monohydrate issued in 1972.<sup>7</sup> When the cephalixin patent expires in 1987, no one will be free to market Keflex because the second patent which specifically covers that compound does not expire until 1989. In short, Lilly will enjoy eighteen years of commercial monopoly on a product which was not even discovered until after the initial patent application covering that product was filed.

These are clearly not isolated examples. The Generic Pharmaceutical Industry Association (GPIA) has documented the fact that the twelve top-selling patented drugs, with U.S. sales of \$1.37 billion in 1980, had an average effective patent life of 18.5 years, and the twenty-five top-selling patented drugs had an average effective patent life of 16.7 years. Obviously, the rules of the patent game were effectively manipulated in those instances to ensure maximum commercial exclusivity.

Apart from patent rules, there are also important investment and marketing decisions which affect the timing and speed of research and development work and, therefore, the length of the commercial monopoly. While much has been said about the adverse impact of regulatory review on the length of effective patent life, until recently little, if any, attention was directed to the fact that the totally discretionary decision as to when a clinical investigation is started and how fast it proceeds has an impact on "effective patent life." An Office of Technology Assessment (OTA) analysis of a Pharmaceutical Manufacturers Association (PMA) chart designed to show that effective patent life for new chemical entities approved in 1980 had shrunk to 7.5 years, establishes that there is a direct correlation between the patent application filing date and the date on which clinical investigations are commenced.<sup>8</sup>

The low average effective patent life figure derived from the PMA

study was significantly influenced by several situations where clinical investigations were not commenced for many years after the composition and its end use were known, and jumps to 11.6 years when these situations are eliminated. PMA claims that this observation is irrelevant since the patent extension legislation would restore only such time as is lost after the patent issues. Significantly, in disputing the relevance of this finding, PMA is in the embarrassing position of disputing one of the key findings in the Eisman and Wardell study on which it has so heavily relied until this point.<sup>9</sup> That study concluded that the starting date of clinical testing is an important factor which influences effective patent life. Wardell also found that for the twelve-year period from 1968 to 1979, for unknown reasons, declining effective patent life can be explained, in part, by a later starting date for clinical testing in relation to the patent application filing date. Rep. Albert Gore, Jr. (D-Tenn.) has correctly observed that these facts demolish PMA's argument that the decline in effective patent life is due solely to delay caused by regulatory review.

Clearly, the search for the definition of "effective patent life," or the belief that meaningful statistics may be developed to establish that it is shrinking as a result of government regulation, is an exercise in futility. Each product has its own unique development, commercialization, and patent history, which makes any generalization in this area highly suspect. An average effective patent life figure which is derived solely by subtracting the NDA approval date from the patent expiration date without considering that history has no validity.

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### **The Proposed Legislation Is Seriously Defective**

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Senate Bill S. 255 provides that ". . . the term of a patent which encompasses within its scope a product, or a method for using a product, subject to a regulatory review, shall be extended by the amount of time equal to the regulatory review. . . ." The term "regulatory review" is defined as the date of initiation of a "major health or environmental effects test," a term defined as an experiment which requires at least six months to conduct. Accordingly, with respect to therapeutic compositions, the extension period would usually commence with the long-term animal toxicity test which precedes the human clinical investigation phase of drug development.

The legislation also provides that the regulatory review period will not be deemed to have started until the patent is actually granted, even though tests which would qualify as regulatory review tests were started prior to that date. Finally, the legislation would go into effect immediately for all therapeutic compositions currently under "regulatory review," although the starting date for measuring the length of the extension

would be the effective date of the legislation.

The interaction between the proposed legislation and some of the basic patent and commercial practices discussed in earlier sections of this paper will clearly result in benefits which go far beyond curing any real or imagined inequity caused by current regulatory practice. The legislation will actually create broad, new, and unwarranted monopoly power. The following are some of the most obvious flaws in the legislation:

- ◆ The starting point for measuring the length of an extension precedes, by a wide margin, the date on which any reasonable and prudent businessman would place a product on the market in the total absence of any regulatory review. Surely, the entire period of long-term animal toxicity testing and clinical investigation cannot be characterized as a “delay” caused by government regulation.
- ◆ The legislation actually rewards delay. As previously noted, effective patent life is shortened when there is a long lapse between the patent application filing date and the commencement of clinical investigations. The legislation provides an incentive for lengthening rather than shortening the gap between these two dates since the regulatory review period is not considered to have started until a patent is actually granted. Accordingly, an innovator who is diligent in commencing a clinical investigation while a patent application is still pending would receive a shorter extension, whereas a party who delays “regulatory review” activities until a patent is granted would actually receive a longer patent extension.
- ◆ The regulatory review process normally relates to a single specific compound and is designed to seek approval to market that compound for a specifically defined end use or indication. As previously noted, patent claims are normally far broader in scope. Thus, a patent which claims a broad hypothetical formula encompassing thousands of compounds would be entitled to an extension, even though the specific compound or end use which is the subject of subsequent regulatory review was not disclosed in the patent.<sup>10</sup> Obviously, the availability of extensions under these circumstances will encourage the filing of even broader and more speculative patent applications and will eventually serve to convert patents from disclosure documents into research proposals. The research “preserve” carved out by such broad and speculative patents, coupled with a patent having a twenty-four year life, will surely serve to discourage third party investigation into the area defined by the patent.
- ◆ The extension legislation may induce the owner of a patent covering a commercially significant product to invest the time and money needed to obtain regulatory approval of some commercially insignificant new therapeutic use because the patent extension would apply to the

product, and not merely the specific new use which is subject to regulatory review. S. 255 contains the following limitation with respect to the scope of any patent extension:

The rights derived from any claim or claims of any patent so extended shall be limited in scope during the period of any extension to the product or method subject to the regulatory review period and to the statutory use for which regulatory review was required.

Since the extended rights are limited to "the product or method" and not "the product and method" which is subject to regulatory review, a product patent claim would be enforceable against all methods of using that product for therapeutic purposes, both old and new, during the period of any extension. The prospect of seven additional years of monopoly prices on an important drug such as Valium can certainly justify a large expenditure of research dollars on an unimportant new use for that composition as a means of extending patent life for the commercially significant old uses.

Moreover, as a result of experience gained by the medical community in using an approved drug for an approved indication, it is not uncommon for significant new therapeutic uses to be discovered, and these discoveries need not necessarily result from the efforts of the original patent owner. The discovery that Inderal (propranolol) is useful in limiting the size of a heart attack among high risk patients is a recent example of such a discovery which was funded by the government. Is the owner of the Inderal patent now properly entitled to up to seven years of additional patent protection on the product simply because it now files an NDA for the independently discovered new end use? Is there any justification for granting an extension of a scope that would provide monopoly power and monopoly prices over the original end uses of Inderal as to which the innovator has already obtained the full benefits of a patent monopoly? Will companies other than the original patentees invest time and money in developing new uses for previously patented drugs, if the discovery of those new uses will lead to extensions of the original patents, thereby blocking them from commercially exploiting the new uses? The legislation does not even recognize that these problems exist, let alone deal with them in any effective manner.

To the extent that government regulation causes delay in bringing products to market, that problem should be addressed and solved. The solution to the problem does not, however, reside in tampering with the patent system in a manner which will create broad new monopoly rights that extend well beyond any real or imagined problem caused by premarketing regulation of drug products.

## NOTES

1. Motion Picture Patents Company v. Universal Film Manufacturing Co., 243 U.S. 871, 876 (1917).
2. In most other industrialized countries, the one year grace period does not exist, and any disclosure or use prior to filing a patent application bars the patent grant. Since most pharmaceutical patent applications are filed internationally, it is normally the international rules which control the decision as to when applications are filed.
3. The “first to file” rule is essentially absolute in most other patent systems.
4. Application of Anthony, 414 F2d 1383 (C.C.P.A. 1969).
5. Anderson, “Patent Term Restoration,” *APLA Journal* 8, no. 4, p. 198.
6. The patent extension legislation would clearly encourage the early filing of broad, speculative patent applications on products of unknown commercial value, since it would permit the patent owner to recapture up to seven years of the time lost as a result of the fact that the commercial embodiment of the alleged invention was unknown when the initial patent application was filed.
7. See U.S. Patent No. 3,507,861 issued April 21, 1970, and U.S. Patent No. 3,655,656 issued April 11, 1972.
8. U.S., Congress, House, Hearings before the Committee on Science and Technology, Subcommittee on Investigations and Oversight, February 4, 1982.
9. Martin M. Eisman and William Wardell, “The Decline in Effective Patent Life of New Drugs,” *Research Management*, January 1981; p. 18.
10. The extension would be limited in scope to the specific product which was subject to regulatory review, but this limitation in the legislation would, nevertheless, permit an extension for an undisclosed product which happens to fall within the scope of a broad patent claim.