

Patent Term Restoration Act Update

How licensing is affected by 1984 Act; language sufficient to address issues suggested

BY WALTER N. KIRN*

The Patent Term Restoration Act of 1984¹ provides for the extension of U.S. patents covering various health-care and food-related inventions² under circumstances specified in 35 U.S.C. §156.

The licensing of patents or patent applications that are or have the potential for being extended requires consideration of the rights and duties of the parties vis-a-vis the extended patent. Relying upon standard or boilerplate licensing language will likely result in confusion and controversy.

There are some obvious areas of concern. Examples include whether the license survives the initial patent expiration date at all, who has authority to seek the extension, who has the right to choose the patent to be extended if multiple patents are eligible for extension, and responsibility of the parties for cooperation in obtaining the extension. Less obvious but certainly important is the scope of the rights derived from the patent during the extension period. Defining the licensed product upon which royalties are payable during the extension period more broadly than the statute permits could have disastrous consequences for the licensor — most likely on the theory of post-patent expiration royalties prohibited under *Brulotte v. Thyss*, 379 U.S. 29 (1964). Licensing definitions appropriate for the conventional patent period should be scrutinized to determine their suitability for the extension term. Until the statute has been authoritatively judicially interpreted, the license drafters might well consider terms that permit redefinition to conform to subsequent interpretations of the law relating to patent term extension.

This paper addresses certain provisions of the act insofar as they give rise to licensing implications, and suggest in some instances at least licensing language designed to address such provisions. The reader will most certainly think of terminology that would better fit his or her needs in a particular licensing context. The purpose here is merely to highlight issues associated with licensing of term-extended or extendable patents without suggesting the particular slant to be taken for a given situation. That will be a matter for negotiation.

1. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

2. Human drug products, medical devices, food additives, and color additives.

*Assistant Chief Patent Counsel, 3M, St. Paul, Minnesota.

ADDRESSING THE EXTENDED TERM

The parties should ascertain whether any of the patents and/or patent applications to be licensed have been extended or are potential candidates for extension. Unless extension is clearly eliminated as a possibility, the parties should address their respective rights and obligations, if any, with respect to the extended patents in the written license agreement. Waiting until the extension is granted before addressing such matters leaves the licensee particularly vulnerable to exaggerated monetary demands from the licensor.

The licensee will normally insist upon a termination clause that survives the seventeenth anniversary of the patent issue date in the event the licensed patent is extended. Certainly, a termination clause that specifies termination as of the seventeenth anniversary date should be avoided if the licensee desires the license during the extended term. Appropriate terminology might be:

Unless previously cancelled pursuant to one of the provisions specified herein, this Agreement shall terminate as of the last to expire of Licensed Patents including any extension of any Licensed Patent.

WHO HAS THE RIGHT TO SEEK EXTENSION

The statute provides that "the owner of record of the patent or its agent shall submit [the] application." 35 U.S.C. 156(d)(1). Unless the license agreement appoints an agent for purposes of submitting the application, the only qualified applicant is the "owner of record," which can only mean the assignee of the patent as shown by the then current Patent Office assignment files. If no assignment is of record in the assignment files, then the owners of record would undoubtedly be the named inventors.

The license agreement should identify the "owner of record" at the time the license agreement is entered into. The entity identified as the "owner of record" should expressly warrant the fact, and must be a party to the agreement at least to the extent of those provisions dealing with authority to submit the extension application.

To illustrate a problem that could arise, assume that an application that is recognized as having the potential for an extended term upon issuance is being licensed to Ajax Corp. There are multiple claims and two persons named as inventors. One is an employee of Bosco Inc., the other is a university professor. The professor has granted Bosco Inc. an exclusive license with right to sublicense under the application and any issued patent in the field of human health care. Bosco has an assignment of the application and any issued patent from its employee on file with the Patent office.

The actual owners of the application are Bosco and the

university professor (assuming the latter is not subject to an agreement to assign to the university). The "owner of record" at the time would presumably also be Bosco and the professor. The statute appears to require that both Bosco and the professor join in the application for extension since neither alone is the owner of record. 35 U.S.C. 262 deals with the rights of joint owners in the absence of an agreement to the contrary. However, it is silent on the right of one joint owner to unilaterally apply for extension of a patent. The prudent licensee would require the university professor to be a party to the agreement at least to the extent of the right and responsibility to apply for the extension. Under the hypothetical, there is no express right granted to Bosco by the professor to sublicense extended patent rights. In some fashion that shortcoming should be cured to assure Ajax that the professor's interests are conveyed as well.

Licensee Concern

Since the owners of record may change after the license agreement is entered into, the licensee must also be concerned with that contingency. Ultimately, the licensee must be assured of the right to require the appropriate applicant at the time to submit the application for extension. The owners of record at the time the license agreement is consummated may be willing to convey the right to apply for the extension to the licensee. If so, this can be done either by appointing the licensee as the owner of record's agent for purposes of submitting the application, or by executing a recordable assignment effective at such time as the patent is eligible for application submission, thereby making the licensee the owner of record for purposes of 35 U.S.C. 156. In any case, it is incumbent upon the licensee to secure contractual provisions binding on the appropriate parties to assure submission of the application for extension.

WHICH PATENT SHOULD BE EXTENDED

The statute limits the number of patents that can be extended for any product to one. 35 U.S.C. 156(c)(4). There may well be two or more patents that are eligible for extension — one claiming the product *per se*, and another claiming the method of using that product to cure the common cold, for example. The two patents could have been the result of two voluntarily filed applications or the result of one application split into two as a result of Patent Office division requirements. If the two patents issued on different dates, they have different expiration dates. If the only consideration is duration of extension, election for extension of the last to issue patent is called for.

Duration may not be the only consideration. Scope of protection may play a more significant role. Here, in particular, the interests of the licensor and licensee may be antagonistic. For example, the licensor may be most interested in prolonging the royalties derived from the licensee and would therefore select for extension a later issued patent covering the method of manufacturing the licensed and approved product rather than a patent claiming the product. The scope of patent rights for the extended term is theoretically broader for the product

patent than the method of manufacture patent. But the licensor may consider the breadth of scope (afforded by the product patent) less important than the extended duration (afforded by the method of manufacture patent). The licensee, on the other hand, may favor the broader scope of the product patent because it eliminates unlicensed competitors that otherwise might be able to introduce product manufactured by a non-infringing method.

The point is that the parties should identify all potential applications and patents extant at the time the license agreement is under negotiation, and should address in the agreement the party having the right to elect the patent for extension in the event multiple patents are otherwise eligible. If there is or will be more than one licensee, a vote by the licensees may be one means of determining the candidate for extension, with the licensor serving as a tie-breaker. Other solutions suggest themselves.

The important thing to keep in mind is to address and resolve the question of selection in the license agreement. While the interests of the licensor and the licensee may be consonant at the time of license consummation, they could diverge at a later date when one of the parties may be in a relatively weaker negotiating position.

Finally, keep in mind the need to have the proper parties agree to any provision dealing with this selection aspect of the extension process as well as the submission of application aspect discussed in the preceding section.

TIMELINESS IN SUBMITTING APPLICATION FOR EXTENSION

The application for extension "may only be submitted within the 60-day period beginning on the date the product received permission...for commercial marketing or use." 35 U.S.C. 156(d)(1). Given the shortness of this period, diligence is required in preparing the application once the triggering event — permission to commercialize — occurs. Written notice of approval to commercialize must be given immediately to the entities responsible for making the application (as well as those who must contribute to the information required for inclusion in the application).

COOPERATION OF THOSE NEEDED TO CONTRIBUTE TO THE APPLICATION

While the owner of record or its agent is the proper applicant of the application, the application itself may require input from more sources than the applicant. For example, 35 U.S.C. 156(d)(1)(D) requires that the application include a brief description of the activities undertaken by the applicant during the applicable regulatory review period. Read literally, this provision would only require a description of activities by the same entity that was making the application for extension. But such application may not have had any role in the activities undertaken during the regulatory review period.

Having prompt access to that information is vital to meet the mandatory filing deadline. If there is concern as to this accessibility at the time the application must be submitted, it would be desirable to secure the information ahead of time, preferably before the license

agreement is consummated, and also obtain written permission to submit that information as part of an application for extension. Getting written agreement of the necessary parties to cooperate fully in submitting the necessary application papers is imperative.

THE SCOPE OF RIGHTS AFFORDED BY EXTENDED PATENTS

Perhaps the most complex provisions of the Patent Term Restoration Act are those dealing with the rights derived from the extended patent. Any confusion in this area is particularly serious because of the patent misuse if not antitrust implications that can arise from such confusion.

There are three parts to the statute dealing with the scope of rights question.

Part (1) deals with patents claiming a product. It reads:

(1) in the case of a patent which claims a product, [the rights will] be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

Part (2) deals with patents claiming a method of using a product:

(2) in the case of a patent which claims a method using a product, [the rights will] be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

Part (3) deals with patents claiming method of manufacture:

(3) in the case of a patent which claims a method of manufacturing a product, [the rights will] be limited to the method of manufacturing as used to make the approved product.

Remembering that only one patent can be extended, if there are three patents each claiming one of the three categories of claims, the applicant can only obtain rights for one of the categories. As between a patent claiming a product, and a patent claiming a method of use, in both cases the extended patent rights are "use" rights. If the patent claiming a method of using a product has method claims that cover *all* the approved uses, then the scope of rights under the product patent would be the same as the rights available under the method of use patent. In that case, all other things being equal (e.g. original issue dates being close or insignificantly different), the applicant may be well advised to opt for the method-of-use patent because the method-of-use claim scope is narrower for validity purposes. In other words, it would be easier to defend the narrower claims against a prior art validity challenge, without any countervailing benefit from the standpoint of infringement.

Third Category

The third category of patents — claiming method of manufacturing — theoretically provides the least rights of the three types. Anyone employing a method of manufacture outside the scope of the claims or outside the method of manufacture used to manufacture the approved product avoids the extended patent. However, if the only commercially feasible method of manufacture is that used to make the approved product and that method is covered by the patent claims then there may

be some justification for electing the method of manufacture patent, especially if duration of extension favors that patent.

35 U.S.C. 156(b)(1) and (2) provides that the extended-patent rights embrace all uses approved prior to the initial patent expiration date, not simply those uses prior to initial expiration that were approved during the regulatory period relevant to calculating the *duration* of the extension. For example, Ajax Corp. obtains an issued patent for a new drug product. An NDA is submitted seeking approval to use the drug as a treatment for acne. It is the regulatory period associated with approval of the drug for use to treat acne that is used to determine the duration of patent term extension. The application for that extension was required to be filed within 60 days of approval to commercialize. An extension of patent term is granted. Four years later, within the original patent term, approval for another use of the drug — treating herpes virus — is sought and obtained. Query. Does the scope of rights derived from the extended patent claiming the product include both the original use (treating acne) and the second use (treating herpes virus). The words of 35 U.S.C. 156(b)(1) and (2) seem to compel an affirmative answer. The only time limitation is that the use be approved for the approved product before the expiration of the term of the patent. Since use for both the acne and herpes virus treatments was approved prior to expiration of the patent term, the patent rights should extend to both uses in accordance with the statutory language.

There is some discomfort in accepting a construction of the statute that extends the scope of the patent rights to all uses approved during the initial patent term. This discomfort arises from the fact that, at least for purposes of determining the duration of extension, only one regulatory review period is considered. Moreover, the time limit for filing the application for extension expires 60 days after the date the product receives the *first* permission for commercial use. The only exception is for patents claiming a method of manufacturing the product while primarily using recombinant DNA technology. Thus, the application for extension occurs before subsequent regulatory review periods have occurred. Moreover, the application for extension is required to contain "information to enable the Commissioner to determine under subsections (a) and (b)...the rights that will be derived from the extension..." 35 U.S.C. 156(d)(1)(C). Such rights can not be determined, at least completely, if subsequently approved uses are eligible for inclusion in the bundle of rights derived from the extended patent.

Scope of Rights

The provision dealing with the scope of rights to be derived from a patent claiming a method of manufacture [paragraph b(3)] is substantially more limiting than the provisions dealing with product [paragraph b(1)] and method of use [paragraph b(2)] patents. Paragraphs b(1) and b(2) employ parallel language. Paragraph b(3) decidedly departs from that language — confining the rights "to the method of manufacturing as used to make the approved products." (emphasis added). Confining the rights to *the* method of manufacture severely limits the scope of protection afforded by the extended patent. At

least as to paragraph b(3), the language appears to preclude including any method of manufacture approved during subsequent regulatory periods, in sharp contrast to the provisions of paragraphs b(1) and b(2) for product and method-of-use patents. Needless to say, confusion as to the scope of rights derived from the extended patent can not be tolerated. In the context of licensing, myriad questions arise. What is the proper basis for royalty payments? If the licensor exacts royalties for activities outside the scope of rights afforded by the extended patent, a misuse violation may exist. *Brulotte v. Thyss*, 379 U.S. 29 (1964). Certainly, if the original license called for royalty payments on product sold for other than approved uses during the original term of the licensed patent, the royalty provision requires modification for the extension period. Moreover, if the license agreement is entered into before all approved uses have been determined, the royalty base will not encompass such subsequent uses. It would seem best to provide a flexible definition for royalty base or at least afford the licensor the right to amend the definition of royalty base to include all approved uses at the time the extended

period begins so long as such users are within the scope of the original patent claims.

CONCLUSION

When a license involves a patent having the potential for extension of term, the license must be drafted to account for the rights and duties of the parties in the event of such extension. Provisions appropriate to licensing the original patent term will most assuredly be inadequate for the period of extension. There is particular need to know the rights derived from the extended patent. The practical difficulty with this is that those rights are not finally determined at least in the case of a patent claiming a product and/or a method of use until the expiration of the original patent. This is because the extended patent rights embraces all uses falling within the scope of the original claims that are approved prior to expiration of the patent. The licensor must have the right to amend the provisions of the license to conform to the appropriate rights determinable at the beginning of the extended term.