

Court Ruling May Lengthen Term of Many U.S. Patents

Overview

In a major victory for patent holders, a federal court ruled on November 1 that the U.S. Patent and Trademark Office's interpretation of the statute governing the term of a patent, which the Patent Office has implemented for the past decade, is wrong. The ruling is expected to lengthen the term of many patents that the Patent Office takes more than three years to grant.

The Patent Office Has Been Short-Changing Patentees

The U.S. Patent and Trademark Office is required by statute to lengthen the term of a patent whose issuance is delayed for any number of reasons. This process, called "patent term adjustment" or "PTA," compensates a patentee for the loss of enforceable patent term, which is measured from the filing date of the patent application. One factor in awarding PTA is whether the Patent Office took more than three years to issue a patent.

Patent Office regulations to implement the patent term adjustment statute include a provision that can reduce the amount of PTA if an applicant takes advantage of a certain procedure to continue examination of an application after the Patent Office closes prosecution. On November 1, the U.S. District Court for the Eastern District of Virginia held that this provision, 37 C.F.R. § 1.703(b), was contrary to the plain language of the PTA statute. See *Exelixis, Inc. v. Kappos*, No. 1:12-cv-96 (slip op.) (E.D. Va. Nov. 1, 2012).

As a result, and assuming that the decision is affirmed in an expected appeal, a significant fraction of future patents, and some existing patents, will be eligible for longer patent terms, which could vary from just days to several years. Even a small period of additional exclusivity afforded by a lengthened patent term can translate into hundreds of millions of dollars in revenue for a pharmaceutical product whose market does not mature until the end of patent life because the early term of the patent was consumed in clinical development.

Congress Changed the Statue Setting the Length of a Patent's Term

Historically, a U.S. patent granted the owner the right to exclude others from making, using or selling the claimed invention in the United States for a term of 17 years. Because the 17-year term began on the date that the patent issued, the time during which an application for the patent application was pending did not affect the length of time that a patent was in force, but instead only shifted that enforceable term later in time.

In 1995, however, the legislation implementing the General Agreement on Tariffs and Trade ("GATT") treaty changed the term of all U.S. patents to expire 20 years after the application for the patent was filed. As a consequence, the time spent in prosecution reduced the length of time during which the patent could be enforced. For example, if a patent application was pending for four years before issuing, then the enforceable term of the patent—the period between issuance and expiration—would be 16 years, one year shorter than the historic 17-year term.

In 1999, in part to remedy the effect of GATT that delays in obtaining a patent would reduce the enforceable term of a patent, Congress enacted the American Inventor's Protection Act ("AIPA"). The AIPA provides patentees with three different guarantees against Patent Office delay in the examination of a patent application, protecting against what are termed "A delay," "B delay," and "C delay." See 35 U.S.C. §§ 154(b)(1)(A), (B), & (C), respectively. The B delay guarantee shown below was at issue in the *Exelixis* case:

§ 154 Contents and term of patent; provisional rights

...

(b) ADJUSTMENT OF PATENT TERM.—

(1) PATENT TERM GUARANTEES.—

...

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

(ii) . . . ,

(iii) . . . ,

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

The goal of the B delay guarantee is to make sure diligent patentees receive at least the traditional 17-year term. The statute provides both a "trigger" condition—if the Patent Office fails to meet the 3-year guarantee—and a "remedy" if the condition is met: "the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued." This remedy is called "patent term adjustment" or "PTA."

The AIPA also introduced section 132(b) in which, under certain circumstances, an applicant can file a request

that the Patent Office consider new evidence or amendments to an application. That process, called a "request for continued examination" or "RCE," permits an applicant to avoid refiling an application or prematurely appealing a rejection before the record is complete. Section 154(b)(1)(B)(i) of the PTA statute provides a continuing examination exception (the "RCE exception") to the B delay guarantee.

The Patent Office's Misinterpretation of the Patent Term Adjustment Statute

At issue in the *Exelixis* case was how to apply the RCE exception, and in particular, whether the RCE exception was an exception to the 3-year calculation of the "trigger" condition or whether it was an exception to the PTA "remedy" provision.

After the AIPA was enacted, the Patent Office promulgated regulations that excluded from the PTA "remedy" the time resulting from the filing of an RCE. The Patent Office thus excluded *any* time "consumed by continuing examination," which in most cases was the time period between filing an RCE and issuance, from accruing as PTA, regardless of when the RCE was filed. In contrast, *Exelixis* argued that the RCE exception should only be applied in determining whether or not the 3-year "trigger" condition is satisfied, meaning that time "consumed by continuing examination" should only prevent PTA from accruing if an RCE was filed before the third anniversary of a patent application.

The Court reasoned that the plain meaning of the statute is "clear, unambiguous, and in accord with both the statute's structure and purpose": the time consumed in continuing prosecution serves to "toll" the 3-year clock, and thus an RCE can impact patent term only if it is filed in the first three years of pendency of an application. *Slip op.* at 11. In effect, the Court agreed with *Exelixis's* argument that the RCE exception only applied to the "trigger" condition.

The statute provides for reduction of PTA when an applicant has "failed to engage in reasonable efforts to conclude prosecution of the application." 35 U.S.C. § 154(b)(2)(C)(i). In arriving at its decision, the Court found it significant that neither the PTA statute nor the regulations governing applicant delay (35 U.S.C. § 154(b)(2)(C) and 37 CFR § 1.704, respectively) consider the filing of an RCE as a failure to engage in reasonable efforts to conclude prosecution. *Slip op.* at 11-13.

The Court rejected other arguments by the Patent Office, and noted that the Patent Office could avoid

unequitable outcomes whereby two similarly situated applicants receive disparate PTA treatment depending on whether they filed an RCE within or outside the 3-year period by controlling the timing of rejections and imposing stricter deadlines for filing RCEs. Slip op. at 15-16.

What's Next, and How to Preserve Your Rights Under the *Exelixis* Decision

This is not the first time that the Patent Office has misinterpreted the patent term adjustment statute and short-changed patentees with their statutory patent term. In 2008, a federal court held that the Patent Office had misinterpreted a different portion of the PTA statute, and in 2010 the U.S. Court of Appeals for the Federal Circuit affirmed that decision. See *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). The Patent Office's response to the 2008 decision is perhaps the best indicator for what will happen next.

In *Wyeth*, the Patent Office did not implement the district court's interpretation of the statute, and instead appealed to the U.S. Court of Appeals for the Federal Circuit, which took approximately one year to affirm the decision holding the Patent Office's interpretation was incorrect. The Patent Office did not appeal further, but finally instituted interim procedures for certain patentees to take advantage of the *Wyeth* decision. However, because such accommodations cannot be guaranteed, applicants and patentees should pay close attention to the statutory and regulatory deadlines for challenging PTA, in order to preserve their rights.

First, an applicant with an allowed application who has filed an RCE after the third anniversary of an application's filing date may want to file a PTA application under 37 CFR § 1.705(b) before or at the time the issue fee is paid. Although the Patent Office has consistently maintained that it does not calculate B delay until issuance and that a 1.705(b) petition concerning B delay is premature, that position is not consistent with the Office's practice of denying B delay after an RCE has been filed, which would allow B delay to be calculated at the time of allowance. Because an applicant might be estopped from making a claim later that could have been made earlier, see 37 CFR § 1.705(d), the safest course is to raise the *Exelixis* issue in a timely 1.705(b) petition.

Second, a patentee who filed an RCE after the third anniversary of an application should file a 37 CFR § 1.705(d) petition on the *Exelixis* issue within two months after issuance.

Third, within 180 days after issuance, such a patentee should file suit as required by 35 U.S.C. § 154(b)(4)(A), regardless whether an earlier 1.705(d) petition has been acted upon. Following the America Invents Act, this lawsuit needs to be filed in the U.S. District Court for the Eastern District of Virginia. Although there is some authority that the 180-day statutory period may be tolled until a 1.705(d) petition is decided, that authority is from a different venue (the District of Columbia) and so cannot not necessarily be relied upon.

Beyond 180 days after issuance, patentees may argue that equitable tolling permits them to retroactively apply for patent term relief. This theory has not been tested in the courts, although there are cases pending that may decide the issue.

Finally, if a patent applicant is considering filing a request for continued examination prior to the third anniversary of an application's filing date, careful consideration should be given to whether it would be beneficial to postpone the filing, if possible, until after the three year anniversary date.

Is a Patent Term Adjustment Bonanza Under Way?

Until November 15, 2009, an RCE was treated as any other response to an Office Action on which examiners were expected to act within two months. After that date, RCEs were handled as "special new" applications and subject to different docketing procedures, without a set time period for an examiner to act. The result of this change in the Patent Office's internal docketing procedure has seen applications with RCEs languishing for several months or more, in some cases about two years, without action. According to recent Patent Office statistics, the backlog of patent applications awaiting examination following the filing of an RCE exceeds 95,000, and the average pendency of an application in which an RCE has been filed is more than five years. If the *Exelixis* decision is upheld on appeal, many of these post-RCE delays will translate to lengthy patent term adjustments.

Conclusion

Patent applicants should strongly consider whether to defer filing an RCE until after the third anniversary of an application's pendency. Where an applicant has filed a request for continued examination after the third anniversary of its application, the *Exelixis* case makes a significant additional adjustment of patent term possible. Patentees concerned about patent term should promptly make sure that they challenge the

Patent Office's faulty determination of B delay for patent term adjustment.



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