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Patents

Extension of Patent Term Doesn't Include Time Spent in Continued Exam, Court Rules

The applicant is responsible for delays in patent allowance incurred by requests for continued examination (RCE), the U.S. Court of Appeals for the Federal Circuit ruled Jan. 15 in a case involving drugmaker Novartis (*Novartis AG v. Lee*, Fed. Cir., No. 2013-1160, 1/15/14).

Accordingly, any patent term adjustment—an extension—wouldn't include the time from the RCE to the date the Patent and Trademark Office allows the patented claims. However, the court said, any time between the allowance and the date the patent actually issues should be calculated as part of the PTA, contrary to the PTO's related rule, potentially increasing the amount of time that can be added to life sciences patents.

In a nonprecedential opinion in a parallel case, the court remanded for recalculation, in light of the *Novartis* opinion, Exelixis Inc.'s request for PTA (*Exelixis, Inc. v. Lee*, Fed. Cir., No. 2013-1175, 1/15/14).

Thousands of patents are issued each year that have been granted after an RCE. There were approximately 80,000 RCEs in progress as of Dec. 31, when the time from RCE request to next office action averaged 7.4 months and, from RCE request to final disposition, 64.8 months.

However, that latter figure includes applications for which patents aren't issued, so it isn't possible to calculate the average time between RCE request and patent allowance—the term relevant patent owners would lose under the Federal Circuit's ruling here.

Some Benefit for Life Sciences Companies. The two opinions represented the CAFC's resolution of two conflicting rulings in the U.S. District Court for the Eastern District of Virginia, one of which found the PTO's interpretation of the PTA statute as it concerns RCEs was incorrect (*Exelixis I*) and the other that found the opposite (*Exelixis II*), and the U.S. District Court for the District of Columbia's ruling in *Novartis*, which agreed with *Exelixis I*. Another district court opinion issued the week before the CAFC's judgments sided with *Exelixis II* (*see related item in this section*).

The *Exelixis I* ruling produced excitement in the life sciences community because it presented the opportunity for companies to increase the amount of time their patents are protected. Jennifer Johnson of Finnegan, Henderson, Farabow, Garrett & Dunner LLP, Washington, told a Biotechnology Industry Organization conference Nov. 12, 2012, that just a few days of additional patent term adjustment can mean millions of dollars in extra revenues for life sciences companies, which is especially important given the years and the amount of investment it takes to develop a drug (6 LSLR 1210, 11/30/12).

The CAFC noted in its ruling in *Novartis* that Novartis, and by extension life sciences companies in the same situation, ''is entitled to most, but not all, of the patent term adjustment it seeks.''

Deborah L. Lu of Vedder Price, New York, told Bloomberg BNA in a Jan. 16 e-mail, ''I think the decision is a win for life sciences law and the patent community, especially because filing an RCE expedites prosecution instead of a lengthier appeal process--even though both periods are subtracted from a patent term adjustment, but the appeal period may be added back if the appeal is favorable to the patent applicant. It seemed unfair to penalize a patent applicant for filing an RCE (which was usually preferable to a patent examiner) to expedite patent prosecution, rather than an appeal, which often results in a delay to obtain a patent with respect to patent term adjustment.''

In other words, Lu said, filing an RCE formerly resulted in a shorter PTA while pursuing an appeal could potentially result in a longer PTA if the appeal was successful. The *Novartis* ruling appears to change that, benefitting life science companies, she said.

Anthony Marshall of Sheppard Mullin Richter & Hampton LLP, told Bloomberg BNA in a Jan. 17 e-mail that the CAFC's ruling ''is a significant shift in patent term adjustment for all patents where prosecution included an RCE filing.''

Marshall advised life sciences companies ''to review their PTA calculations closely, as this decision could extend the life of their patents by days, months or even years.''

PTA, RCE Provisions. Patent term extensions are given for excess time taken by the PTO to approve the patents. Since at least the mid-2000s, plaintiffs have been challenging the PTO's interpretation of the relevant provisions in 35 U.S.C. § 154(b), enacted as part of the Uruguay Round Agreements Act of 1994 and amended under the American Inventors Protection Act in 1999.

Section 154(b)(1)(B) defines ''B'' delays and provides for a day-for-day term extension ''if the issue of an original patent is delayed due to the failure of the [PTO] 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).'' Section 132(b) enables RCEs.

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The PTO's interpretation of the impact of RCEs, in regulation 37 C.F.R. § 1.703(b)(1), says that the B delay doesn't include ''[t]he number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued.''

''A'' delays occur when the PTO misses specific deadlines, such as a first office action.

***Wyeth* Case Launches Controversy.** In 2010, the Federal Circuit decided *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) (4 LSLR 16, 1/15/10). That case didn't involve the RCE issue, but instead concerned the PTO's calculations of PTA when the A and B delay periods overlapped. The Federal Circuit told the PTO that it was coming up short in its PTA calculations under those circumstances.

The PTO then announced that it would permit recalculation of *Wyeth*-related PTA for previously issued patents, so long as the request for reconsideration was filed within 180 days of the grant of the patent (4 LSLR 126, 2/12/10). That effectively meant that a *Wyeth* adjustment would be available to patents issued after Aug. 4, 2009, but limited to that 180-day period.

The 180-day limit is defined, in subparagraphs (3) and (4)(A) of Section 154(b), as to court challenges; the PTO effectively matched that timing with respect to administrative challenges.

Wyeth Applies, but No Tolling. After *Wyeth* was announced, Novartis AG challenged the PTO's PTA calculations on 23 patents, 19 of which were beyond 180 days from issuance. The PTO contested those 19 as untimely filed.

The office didn't dispute the timeliness of Novartis's filings as to the other patents (U.S. Patent Nos. 7,470,792; 7,807,155; 7,968,518 and 7,973,031) but fought Novartis's PTA calculations on them.

Judge Ellen Segal Huvelle of the U.S. District Court for the District of Columbia concluded that the PTA requests for each of the contested 19 patents were untimely (*Novartis AG v. Kappos*, 904 F. Supp. 2d 58, 2012 BL 299234 (D.D.C. 2012) (6 LSLR 1175, 11/30/12)). Novartis appealed as to 15 of the 19 patents held untimely filed.

Huvelle ruled against the PTO on the other four, though. The issue on the '792 patent related to a *Wyeth*-type A/B delay overlap and was not contested before the Federal Circuit.

For the other three, the issue related to an RCE. Huvelle ruled that PTA accrued during the RCE and up to the date of issuance. The PTO appealed that judgment.

180 Day Statutory Limit. The Federal Circuit appeals court, in an opinion written by Judge Richard G. Taranto, first addressed the 180-day statutory limit.

The issue was one of statutory interpretation of Sections 154(b)(3) and (b)(4)(A). The court concluded that Novartis had identified ''a flaw in drafting'' in the text of the sections, but noted that, in the America Invents Act, ''Congress recognized the flaw and altered the language'' to match the PTO's reading of the provision.

The court rejected Novartis's alternative argument that the 180-day limit should be equitably tolled based on waiting for the *Wyeth* decision. ''A fortiori equitable tolling is unavailable where, as here, there is no reason even to doubt that the litigant knew the legal theory, but just waited until another person secured a favorable ruling on the theory in another case,'' the court said. And the court said that Novartis's Fifth Amendment takings claim was unavailable because of the untimely filing.

Thus, the court affirmed the lower court's judgment to the 15 patents appealed on that issue.

PTO Found Half Right. The court then turned to the RCE issue and the three patents that were still eligible for PTA. It agreed with the PTO's first argument, that the time spent in RCE was attributable to the applicant and so should not be added to the PTA.

The court thus held that ''the correct interpretation of the statute is the PTO's view that time spent in a continued examination does not deplete the PTO's allotment of three years for application processing before a resulting patent has its term extended, no matter when the continued examination begins.''

However, the court determined that the PTO was wrong to argue that the RCE exclusion extended after the date the PTO allowed claims until the date of issuance.

''Such time from allowance to issuance undisputedly would count toward the PTO's three-year allotment in a case not involving a continued examination,'' the court said. ''There is no basis for distinguishing a continued-examination case.''

That time is ''consumed'' by the PTO, the court said, as ''the application moves from the examiner to the office of publication.''

And because the PTO's calculations for the three patents at issue here subtracted that time, the court remanded for recalculation.

Judges Pauline Newman and Timothy B. Dyk joined the opinion.

District Court *Exelixis* Decisions. *Exelixis Inc. v. Kappos* was decided by the U.S. District Court for the Eastern District of Virginia in two separate opinions (919 F. Supp. 2d 689, 2013 BL 23256 (E.D. Va. 2013) (7 LSLR 137, 2/8/13), for U.S. Patent No. 8,067,436, and 906 F. Supp. 2d 474, 2012 BL 290038 (E.D. Va. 2012) (6 LSLR 1135, 11/16/12) for U.S. Patent No. 7,989,622). Both PTA calculations at issue were related to RCE delays.

''Based on the ruling in *Novartis*, we vacate the judgments as to patent term adjustment for the '436 and '622 patents in this case and remand for redetermination of the proper adjustments in accordance with *Novartis*,'' the same three members of the court said in a per curiam opinion.

Scott S. Christie of McCarter & English, Newark, N.J., represented Novartis. J. Michael Huget of Honigman Miller Schwartz and Cohn LLP, Ann Arbor. Mich., represented Exelixis. The PTO was represented in both cases by Dana Kaersvang of the U.S. Attorney's Office, Washington, D.C.

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Text of the Novartis opinion is available at http://www.bloomberglaw.com/public/document/Novartis_AG_v_Lee_Docket_No_1301160_Fed_Cir_Jan_14_2013_Court_Doc.

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Text of the Exelixis opinion is available at http://www.bloomberglaw.com/public/document/Exelixis_Inc_v_Lee_Docket_No_1301175_Fed_Cir_Jan_18_2013_Court_Do.