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Pharmaceutical and medical device companies strive to maximize patent term as lengthy development and regulatory review processes precede commercial sales. Most patents internationally receive a standard term of 20 years from the initial application filing date. But US patents frequently receive a longer term, mainly due to patent term adjustment (PTA). PTA offers extra patent term to compensate for certain application processing delays at the United States Patent and Trademark Office (USPTO). About 70–80% of US patents receive some PTA, with an average PTA award of about 10–12 months [1]. In addition to PTA, US pharmaceutical and device patents may receive extra term due to regulatory delays at the Food and Drug Administration, while submission of a terminal disclaimer may also shorten a patent term by linking together two related patents so that they expire on the same day and remain commonly owned.

While a simple concept, in practice, PTA requires complicated balancing between USPTO delays and applicant delays. Three types of USPTO delays give rise to additional patent term, nicknamed 'A delay,' 'B delay' and 'C delay.' These occur when: the USPTO takes more than allowed to begin examination or to respond to certain applicant papers; the application takes more than 3 years to issue as a patent; or patent issuance is delayed due to an appeal, secrecy order or derivation proceeding [2]. A patent receives one day of extra term for each day of A, B or C delay, after subtracting any overlaps (i.e., when more than one type of delay occurs on the same date). The USPTO then subtracts 'applicant delay' from the total nonoverlapping A, B and C delay period to obtain the overall PTA award. Applicant delay occurs when an applicant takes longer than permitted to respond to certain USPTO papers or files certain papers after allowance [3].

Novartis v. Lee concerns the way in which the USPTO calculates the B delay period (for applications pending longer than 3 years) when an applicant files a Request for Continued Examination (RCE) in response to a final rejection, in order to continue negotiations with the patent examiner [4]. An RCE is a device for re-opening examination after the examiner has closed it, for example, due to final rejection of the application. Without an RCE, B delay is simply the number of days from application filing to patent

issuance that extend beyond 3 years. But when an applicant files an RCE, the USPTO had calculated the B delay as the number of days from application filing date to first RCE filing date that extend beyond 3 years. In other words, filing an RCE terminated the B delay period. Novartis argued to the court that the USPTO had misinterpreted the underlying law, and that when an applicant files an RCE before allowance of the application, the B delay should only be reduced by the period between RCE filing and allowance of the application. In Novartis's opinion, B delay should include the period from allowance of the application to issuance of the patent, usually several months. The court agreed. Accordingly, the court decision requires the USPTO to award a longer term to most patents that are pending for more than 3 years and have at least one RCE filing before allowance.

USPTO rule changes following *Novartis*
Although the *Novartis* decision published in January 2014, the USPTO did not issue final rule changes to implement the decision until 9 January 2015 [5]. In June 2014, the USPTO published proposed rule changes [6]. Several individuals and groups, including the American Intellectual Property Law Association (AIPLA), the Intellectual Property Owners Association (IPO) and the Pharmaceutical Research and Manufacturers of America (PhRMA) made public comments on those proposals in August 2014 [7]. The USPTO's final rule package revises the earlier proposals and addresses those public comments.

The USPTO first amends Rule 1.703(b)(1), pertaining to calculation of B delay when the applicant files an RCE. The language of the amended rule follows the previous proposal. Specifically, the rule cuts off from the B delay the period from the filing date of an RCE up to the mailing date of a Notice of Allowance. Comments on the previous proposal argued that this rule results in a PTA that is one day shorter than set forth in the court decision and that the mailing date of the Notice of Allowance should not be excluded from the B delay [8]. But the USPTO disagreed and did not revise the language.

The USPTO states that the revised Rule 1.703(b)(1) will apply to newly granted patents as well as retroactively to previously issued patents [9]. But the USPTO also clarifies that the rule will not apply retroactively to previously issued patents unless the patentee had timely petitioned for a PTA recalculation in light of *Novartis* [10]. Specifically, under Rule 1.705(b) a patentee must petition for PTA recalculation within 7 months of patent issuance or any additional term that could have been awarded is waived. A patentee may also appeal an adverse USPTO petition decision in court if necessary. The USPTO notes that it has calculated B delay according to these new rules since 7 October 2014, implying that patents issued before that date will not receive a complete PTA award accounting for *Novartis* unless the patentee filed a timely petition requesting it [11].

The USPTO also revises Rule 1.704(c) to create a new form of applicant delay for the filing of an RCE after receipt of a Notice of Allowance. RCEs are mainly filed after allowance to submit an Information Disclosure Statement (IDS) containing copies of prior art references or other materials relevant to the application. A postallowance RCE restarts examination, as the application returns to the examiner. Once the examiner reaffirms patentability, the USPTO will issue another Notice of Allowance.

The new USPTO rules will now treat many such postallowance RCEs as applicant delays. Under new Rule 1.704(c)(12), filing an RCE after allowance will reduce the overall PTA by the period from the day following the initial Notice of Allowance up to the RCE filing date. This rule change did not go into effect until 10 March 2015, however, and thus, will not impact RCEs filed prior to that date.

The changes to Rules 1.703 and 1.704 taken together mean that, if an applicant files an RCE after allowance and then receives a new Notice of Allowance, the PTA award will not include any of the time from the first allowance to the subsequent allowance. Specifically, the time from the day after the first allowance to the RCE filing is applicant delay, and the time from RCE filing to the subsequent allowance is excluded from the B delay.

Public commenters criticized the change to Rule 1.704 as outside the scope of the *Novartis* decision, among other reasons, but the USPTO did not withdraw it [12]. In the USPTO's view, without this rule change, an applicant could use a postallowance RCE in order to delay patent issuance and add to the PTA award [13].

The USPTO added an exception to this new rule, however, in response to the public comments [14]. Specifically, under revised Rule 1.704(d)(1), a postallowance RCE does not cause applicant delay if it is accompanied only by an IDS, and the applicant also certifies: that the IDS lists only references "*first cited in any communication from a patent office in a counterpart… application or from the (USPTO)*" or a patent office communication itself, and that the communication submitted with the IDS or listing the cited references was first received within 30 days of the RCE/IDS submission. This same exception already applies to IDSs submitted at earlier points during prosecution.

Conclusion

Collectively, these rule changes strongly encourage patent applicants to pay close attention to their information disclosure practices and to review Notices of Allowance quickly upon receipt. Applicants may wish to review the application and information disclosure status at particular points during examination in order to avoid submitting papers after allowance. And while some postallowance IDSs may not result in an overall loss of PTA, applicants should treat with care the required certification statements to avoid such a PTA loss. Thus, these rules as a whole, along with many other USPTO rules, strongly encourage early IDS submissions as a strategy for maximizing US patent term.

References
1 Crouch D. USPTO Continues to Reduce Patent Term Adjustments. http://patentlyo.com
2 *See* 35 U.S.C. § 154(b)(1)(A), (B), and (C).
3 *See* § 154(b)(2)(C).
4 *Novartis AG v. Lee,* 740 F.3d 593 (Fed. Cir. 2014).
5 80 Fed. Reg. 1346.
6 79 Fed. Reg. 34,681.
7 USPTO gov. www.uspto.gov/patents/law
8 AIPLA letter of August 13, 2014, at 5; IPO letter of August 18, 2014, at 2; PhRMA letter of August 18, 2014, at 2. www.uspto.gov
9 80 Fed. Reg. at 1346, 3rd column.
10 *Id.* at 1348, 1st column.
11 *Id.*

12 AIPLA letter at 2–3; IPO letter at 4–5; PhRMA letter at 4.
13 80 Fed. Reg. at 1348, 2nd column.
14 See AIPLA letter at 2–3; IPO letter at 4–5; PhRMA letter at 4.