

## Federal Circuit Patent Bulletin: *Daiichi Sankyo Co. v. Lee*

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July 6, 2015

*"[T]he PTO did not abuse its discretion by determining not to accept petitions for administrative review filed more than 180 days after the patent grant."*

On July 2, 2015, in *Daiichi Sankyo Co. v. Lee*, the U.S. Court of Appeals for the Federal Circuit (Moore, Reyna,\* Taranto) affirmed the district court's summary judgment that the U.S. Patent & Trademark Office (PTO) did not violate the Administrative Procedures Act and 35 U.S.C. § 154(b) by miscalculating the patent terms for U.S. Patents No. 7,342,014 and No. 7,365,205, which related to compounds for treating tissue death due to lack of oxygen, blood clots, and other ailments. The Federal Circuit stated:

Section 154 of the Patent Act restores a patent's term for two types of delay during patent prosecution that are attributable to the PTO. The first type of delay, "A Delay," arises when the PTO fails to meet statutory deadlines for events that occur during prosecution, such as providing notice to the applicant of the rejection of a claim or taking action on an applicant's reply to such a rejection. The second type of delay, "B Delay," arises when, through the fault of the PTO, the agency fails to issue a patent within three years after the actual filing date of the patent's application. Two patent term adjustment determinations are made prior to the issuance of a patent. First, when the PTO determines that a patent is in condition for allowance, the agency will make an initial determination and will "transmit a notice of that determination with the written notice of allowance of the application" to the applicant. At the time of issuance, and upon a timely request for reconsideration that satisfies the regulatory requirements, the PTO will make a final determination, which it then prints on the face of the patent.

A patentee who is dissatisfied with the number of days restored to the term of the patent has a statutory right to both administrative and judicial review. Regarding administrative review, the statute requires the Director of the PTO to provide a patentee one opportunity to request reconsideration of any patent term adjustment determination made by the agency. The statute instructs the Director to prescribe regulations that create the procedures for challenging the determination at the agency. The PTO promulgated 37 C.F.R. § 1.705, which imposes a deadline for requesting that the agency reconsider the patent term adjustment determination, stating that "any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued." Additionally, a patentee can seek judicial review of the agency's patent term adjustment determination.

Prior to 2010, the PTO's practice was to restore, upon issuance, patent term equaling the greater of the number of days of A and B Delays occurring during prosecution. [Federal Circuit precedent now requires] the PTO to extend a patent's term for every day of A or B Delay where those delays did not occur on the same day, and to extend the term by one day for each day the A and B Delays did occur on the same day. [T]he PTO adopted an "Interim Procedure" for requesting patent term adjustments. The Interim Procedure set out the procedure by which a patentee could request reconsideration within two months of the patent issuance date. The Interim Procedure also adopted an "optional" procedure ("Optional Interim Procedure") for patents that issued before March 2, 2010.

Under the Optional Interim Procedure, patentees could file a petition for reconsideration up to 180 days after the issuance date, provided the sole basis for the request was that the patent term adjustment was made under the PTO's pre-Wyeth adjustment calculation method. The net result of the specified date and filing window was to make the Optional Interim Procedure available for patents that issued from August 5, 2009 (the earliest date of availability of the Optional Interim Procedure) to March 1, 2010. Petitions filed outside this 180day window would be "den[ie]d as untimely." This appeal involves Daiichi's challenge to the PTO's denial of Daiichi's requests for reconsideration of the patent term adjustments for two of its patents. . . .

Here, we agree with the government that the PTO has not erroneously interpreted the law. Rather, the agency acted within its discretion under the statute to "prescribe regulations establishing procedures for the . . . determination of patent term adjustments," in adopting the 180-day period as part of the Interim Procedure. Similarly, the PTO acted within its discretion in denying Daiichi's requests for reconsideration of the patent term adjustment determinations. Both decisions provide ample reasoning for considering only requests filed within 180 days of the patent grant. The PTO points to the 180day statutory judicial review period and notes that it is shorter than the normal six-year statute of limitations for administrative challenges under the APA. The PTO explains that this brief period for judicial review indicates Congress' intent that it resolve patent term adjustment issues more expeditiously than allowed under the full administrative challenge period. The PTO also reasoned that it was unlikely that Congress intended for the period for administrative review to extend beyond the period in which that administrative review could be challenged in the district court.

The PTO's decisions are consistent with the law in effect at the time of the decisions, including all of § 154's provisions. The PTO's conclusion that its authority to conduct administrative reviews extends no further than the period for judicial review is also consistent with the statute, which expressly authorizes the PTO to make regulations governing the procedures of patent term adjustment reconsiderations. As such, we find that the PTO did not abuse its discretion by determining not to accept petitions for administrative review filed more than 180 days after the patent grant. . . .

We conclude that Daiichi has not shown that the PTO treated any requests for reconsideration of patent term adjustments filed for patents issuing before August 5, 2009 differently than Daiichi's petitions. All other similar requests were denied by the agency, showing that the PTO acted consistently with respect to similarly situated patentees. Accordingly, the PTO did not act arbitrarily or capriciously based on its treatment of reconsideration requests submitted by similarly situated patentees.

[Daiichi argues that] the government acts arbitrarily whenever it opposes a patentee that seeks recalculation under the agency's new calculation method for patents issued prior to the Optional Interim Procedure's earliest qualifying date. We disagree. . . . Further, there is no indication that counsel was acting with authority to bind the government so as to prevent it from ever disputing that a patent issuing before the earliest qualifying date for the Optional Interim Procedure is not entitled to a recalculation under the new calculation method. We must also consider whether the agency's choice to grant extensions of the administrative review period for some patents to match the judicial review period for all patents was arbitrary and capricious. [A]ll patentees who could take advantage of the Optional Interim Procedure could still challenge their patent term adjustment in the district court under the statute. The PTO simply provided an alternative, and more cost-effective, mechanism at the agency for attaining the same result. Choosing an administrative filing deadline that mirrors the judicial filing deadline, especially when it lengthens that deadline for some patentees, is neither arbitrary nor capricious.