# United States Court of Appeals for the Federal Circuit

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**INTRA-CELLULAR THERAPIES, INC.,**
*Plaintiff-Appellant*

**v.**

**ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,**
*Defendant-Appellee*

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2018-1849

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Appeal from the United States District Court for the Eastern District of Virginia in No. 1:17-cv-00776-CMH-IDD, Senior Judge Claude M. Hilton.

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Decided: September 18, 2019

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THOMAS HOXIE, Hoxie & Associates, LLP, Millburn, NJ, argued for plaintiff-appellant.

ANDREW SUN HAN, Office of the United States Attorney for the Eastern District of Virginia, Alexandria, VA, argued for defendant-appellee. Also represented by G. ZACHARY TERWILLIGER; KAKOLI CAPRIHAN, THOMAS W. KRAUSE, JOSEPH MATAL, BRIAN RACILLA, Office of the Solicitor,

United States Patent and Trademark Office, Alexandria, VA.

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Before WALLACH, CHEN, and HUGHES, *Circuit Judges.*

CHEN, *Circuit Judge.*

Intra-Cellular Therapies, Inc. (Intra-Cellular) appeals the summary judgment decision of the United States District Court for the Eastern District of Virginia affirming the patent term adjustment (PTA) determination made by the United States Patent and Trademark Office (Patent Office). During prosecution of Intra-Cellular's patent application, the Patent Office issued a final Office action rejecting some claims and objecting to the others. A final Office action, as opposed to a non-final Office action, marks the end of formal prosecution of an application. On the three-month deadline for responding to the final Office action, Intra-Cellular filed its first response. While timely, this initial response continued to argue the merits of the examiner's final rejections and failed to comply with the Patent Office's regulatory requirements for what constitutes a proper "reply" to a final Office action. For that reason, the Patent Office concluded that Intra-Cellular's first response did not prevent the accrual of applicant delay for purposes of calculating PTA for the resulting patent. Twenty-one days after filing its unsuccessful first response, Intra-Cellular tried again by filing a second response. This time, Intra-Cellular successfully overcame all outstanding rejections and objections. Adopting all of the examiner's suggestions, the second response capitulated to all of the examiner's rulings by canceling or amending every rejected or objected to claim based on the examiner's positions. As a result of these amendments, the Patent Office issued a Notice of Allowance and concluded that this second response stopped the accrual of any further applicant delay. In calculating PTA, the Patent Office determined that the extra 21 days it took Intra-Cellular to file a successful

response after the three-month deadline for responding to the final Office action constituted applicant delay. Because we find that determination of applicant delay was based on a permissible interpretation of statute and proper reading of the regulations, we affirm the district court's grant of summary judgment in favor of the Patent Office.

## BACKGROUND

### I. Statutory Framework

Patent term constitutes the period of exclusivity in which a patent is in effect. In 1994, Congress amended the law to change the period of patent term from 17 years from issuance to 20 years, measured from the earliest filing date of the application for patent. *See* Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994) (codified as amended at 35 U.S.C. § 154(a)). Due to this change in the law, if the Patent Office issued a patent two years after its filing date, the resulting patent would enjoy 18 years of patent term. But if a favorable patent examination took, say, seven years to complete, then there would only be 13 years of patent term remaining after issuance, far less than the 17-year term provided for under the prior law. To protect patent owners against loss of patent term due to agency delay in the patent examination process, Congress amended § 154 in 1999 to restore patent term under certain circumstances. *See* Pub. L. No. 106-113, § 4402, 113 Stat. 1501, 1501A-557 (1999) (codified as amended at 35 U.S.C. § 154(b)) (PTA statute). Under the PTA statute, the term of a patent can be extended to compensate for lost patent term due to statutorily-defined agency delay. *See* § 154(b)(1)(A)–(C). But, at the same time, PTA can be reduced for delays caused by the applicant. *See* § 154(b)(2)(C).

Section 154(b)(1) provides three types of statutorily-defined delay caused by the Patent Office that will lead to accrual of PTA for the resulting patent, outlined in § 154(b)(1)(A), (B), (C). "A Delay" accrues when the Patent

Office fails to act by certain examination deadlines. § 154(b)(1)(A). "B Delay" accrues when the Patent Office fails to "issue a patent within 3 years after the actual filing date of the application." § 154(b)(1)(B). "C Delay" accrues during the pendency of interferences, secrecy orders, and appeals. § 154(b)(1)(C).

On the other hand, when *applicant* conduct causes delay in the examination process, any PTA that has accumulated is reduced by that amount of applicant delay. *See* § 154(b)(2)(C); *Gilead Scis., Inc. v. Lee*, 778 F.3d 1341, 1344–45 (Fed. Cir. 2015). Under § 154(b)(2)(C)(i) of the PTA statute, a patent's PTA "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application."

Section 154(b)(2)(C)(ii) provides an instance of what constitutes "fail[ure] to engage in reasonable efforts" based on how long it takes for an applicant to respond to certain Office actions. In particular, "an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the [Patent] Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant." § 154(b)(2)(C)(ii).

Section 154(b)(2)(C)(iii) authorizes the Patent Office to promulgate regulations providing further details and examples of what constitutes "fail[ure] to engage in reasonable efforts." This regulation provides that the "Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." § 154(b)(2)(C)(iii).

## II. Regulatory Framework

Pursuant to its congressional authority, the Patent Office promulgated regulations for determining PTA reduction due to applicant delay. Relevant to this appeal is 37 C.F.R. § 1.704(b), which closely tracks the language in § 154(b)(2)(C)(ii). This regulation provides that "*an applicant shall be deemed to have failed to engage in reasonable efforts to conclude* processing or examination of an application for the cumulative total of *any periods of time in excess of three months that are taken to reply* to any notice or action by the [Patent] Office making any rejection, objection, argument, or other request . . . ." § 1.704(b) (emphases added). In other words, if an applicant takes longer than three months to file a "reply" to an Office action, applicant delay will accrue. Applicant delay begins accruing from the day after the three-month deadline for responding to an Office action and stops accruing the "date the reply was filed." § 1.704(b). But § 1.704(b) itself does not define what constitutes a proper "reply" for cutting off applicant delay.

Section 1.704(b) was promulgated against a backdrop of long-existing regulations governing patent prosecution practices. One fundamental principle that pervades these regulations is that a "final" Office action marks the end of normal prosecution as of right. *See* 37 C.F.R. § 1.113(a), (c); § 1.114(b) ("Prosecution in an application is closed as used in this section means . . . that the last Office action is a final action . . . ."); MPEP § 714.12 ("Once a final rejection that is not premature has been entered in an application, applicant or patent owner no longer has any right to unrestricted further prosecution."). Before a final Office action is issued, an applicant has more leeway to argue its case and amend its claims in a reply. To properly respond to a non-final Office action, a "bona fide attempt to advance the application" is required. *See* 37 C.F.R. §§ 1.111(b), 1.135(c). Once examination proceeds into after-final Office action territory, however, § 1.113(a) restricts the options that are available to the applicant, and the patent

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