



A Note on Mayo Foundation for Medical Education and Research v. Iancu

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Recommended Citation

Florence Montarmani, *A Note on Mayo Foundation for Medical Education and Research v. Iancu*, 30 DePaul J. Art, Tech. & Intell. Prop. L. 90 (2020)
Available at: <https://via.library.depaul.edu/jatip/vol30/iss1/3>

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**A NOTE ON MAYO FOUNDATION FOR MEDICAL EDUCATION AND
RESEARCH V. IANCU**

*Florence Montarmani**

I. INTRODUCTION

The beauty and appeal of obtaining a patent lies in the right to use a specific invention for a 20-year period after issuance.¹ The clock begins ticking from the filing date of the application.² However, much of the 20-year term is consumed during the prosecution of a patent: the time between filing a patent application and receiving approval from the United States Patent and Trademark Office (“USPTO”).³ Patent prosecution can be a burdensomely, time-consuming process that averages approximately 23.8 months—just shy of two years.⁴

Delays in prosecution of a patent effectively reduce the enforceable term of the patent by eating away at the 20-year exclusivity term.⁵ As a solution to this disparity, the USPTO adopted the Patent Term Adjustment (“PTA”).⁶ The PTA compensates an applicant for “lost time” by extending the life of the patent on a day-by-day basis, adding one day to the end of the patent’s life span for each day delayed by the USPTO during

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¹ Department of Commerce Patent and Trademark Office, 37 C.F.R. Parts 1 and 3 *Changes to Implement 20 Year Patent Term and Provisional Applications*, <https://www.uspto.gov/web/offices/com/sol/og/con/files/cons096.htm>

² *Id.*

³ Westlaw Practical Law: *Patent Application Prosecution Overview*.

⁴ IP Spotlight: *How long does it take to get a patent or trademark? (2018 Update)* (Jan 11, 2019), <https://www.jdsupra.com/legalnews/how-long-does-it-take-to-get-a-patent-21821/>

⁵ Dale Fresh, Scott Harper, 2019 TXCLE-AIP 6-V: *Patent Term Adjustment*

⁶ *Id.*

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prosecution.⁷ The idea of the USPTO repaying lost time seems simple. But there are several concepts that complicate how much time will be allotted to an applicant.

Part II of this case note will focus on the historical reasoning behind Patent Term Adjustments and how to calculate different types of delays.⁸ Part II will further explain applicant interferences with PTAs and the idea behind double patenting laws.⁹ Part III will focus on the central case for this note, *Mayo Foundation for Medication Education and Research v. Iancu*.¹⁰ Part IV will analyze the majority's holding and dissent's argument and discuss which application of the law was correct.¹¹ Part V will discuss the implications the holding of *Mayo Foundation* has on future patent applications and how patent term adjustments and extensions relate to double patenting.¹² Part VI will summarize why this case topic is of growing concern in patent law.¹³

II. BACKGROUND

The idea of a patent term adjustment was conceived by Congress in 1994.¹⁴ Enactment of the Uruguay Round Agreements Act (URAA) led Congress to extend the life of a patent from 17 years, beginning on the effective date of issuance, to twenty years from the date of filing.¹⁵ The patent term was extended to compensate for delays in patent prosecution that occur between the filing of an application and the date of the final issuance.¹⁶ Five years later, in 1999, Congress expanded the terms of the PTA by

⁷ Perkins Coie, LLP. *What is Patent Term Adjustment and Why Does It Matter?* (June 30, 2014)

⁸ See *infra* notes and accompanying text.

⁹ See *infra* notes and accompanying text.

¹⁰ See *infra* notes and accompanying text.

¹¹ See *infra* notes and accompanying text.

¹² See *infra* notes and accompanying text.

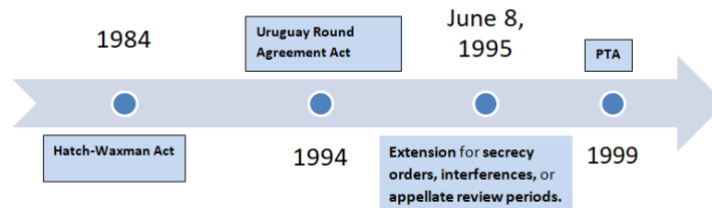
¹³ See *infra* notes and accompanying text.

¹⁴ *Mayo Foundation for Medical Education & Research v. Iancu*, 2019 U.S. App. LEXIS 27771 (Fed. Cir. Sept. 16, 2019).

¹⁵ *Id.*

¹⁶ *Id.*

adding three classes of “delays” that could qualify an applicant for adjustment.¹⁷



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The premise behind this note begins with the issue of patent term adjustments as laid out in the case of *Mayo Foundation for Medical Education and Research v. Iancu*.¹⁹ Although it seems like a simple concept, the effects of decisions made by the Federal Circuit in cases such as *Mayo Foundation*, and several others in recent years will have major implications on a larger area of patent law known as double patenting.²⁰ In order to understand the relationship, it is important to grasp the concepts individually:

A. Patent Term Adjustment

The foundation of Patent Term Adjustments is laid out in section 154(b) of the Patent Act.²¹ The Act provides three different circumstances where a patent may be granted an extension of the

¹⁷ *Id.*

¹⁸ Timeline shows history of patents as they have evolved into having a 20-year term. Legal Advantage, *A Practical Approach to Calculating Patent Term Adjustment (PTA)* (Oct. 17, 2018) <https://www.legaladvantage.net/blog/a-practical-approach-to-calculate-patent-term-adjustment-pta/>

¹⁹ *Mayo Foundation for Medical Education & Research v. Iancu*, 2019 U.S. App. LEXIS 27771 (Fed. Cir. Sept. 16, 2019).

²⁰ Janice Mueller, *Aspen Student Treatise Series: Patent Law* (5th Edition, 2016) “Double patenting is often charged against pharmaceutical firms allegedly engaged in ‘ever-greening,’ that is, obtaining a series of patents on closely related drug inventions in an attempt to improperly prolong the patent life of the firm’s products.”

²¹ USPTO.gov, *35 U.S.C. 154 Contents and term of patent; provisional rights*, <https://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-1.html#d0e303482>

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patent term, referred to as “delays.”²² The USPTO has categorized the three kinds of delays where an applicant may be entitled to an adjustment: A delay, B delay, and C delay.²³

35 U.S.C. § 154(b)(1)(A) describes an A delay.²⁴ This type of delay lies in the idea that the USPTO should give prompt responses. Specifically, an A delay is appropriate when:

- (i) the USPTO fails to issue a notice, i.e., mail a restriction requirement, a non-final office action, or a notice of allowance, within 14 months after the application filing date
- (ii) the USPTO fails to respond to an applicant’s Reply within 4 months
- (iii) the USPTO fails to respond to a Patent Trial and Appeal Board (PTAB) decision within 4 months
- (iv) the USPTO fails to issue a patent within 4 months after issue fee has been paid.²⁵

For an A delay, the patent term is extended by one day for each day after the end of each specified period in the statute.²⁶

35 U.S.C §154(b)(1)(B) explains a B delay as proper where the USPTO fails to issue a patent within 3 years from its filing date.²⁷ B delays exclude time consumed by requests for continued examination (“RCE”) and, appeals or interferences.²⁸

Finally, 35 U.S.C. §154(b)(1)(C) states C delays provide adjustment for interferences, secrecy orders, and appeals.²⁹ An

²² Christina Sperry, Elissa M. Kingsland, *Patent Term Adjustment: The Real Meaning of Applicant Delay* (Feb. 26, 2019), <https://www.mintz.com/insights-center/viewpoints/2231/2019-02-patent-term-adjustment-real-meaning-applicant-delay>

²³ 35 U.S.C. § 154(b)(1)

²⁴ 35 U.S.C. § 154(b)(1)(A).

²⁵ *Id.*

²⁶ *Id.*

²⁷ 35 U.S.C. § 154(b)(1)(B).

²⁸ *Id.*

²⁹ 35 U.S.C. § 154(b)(1)(C).

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appeal can be contributed in a C delay only if it is successful.³⁰ An unsuccessful appeal terminates the “B” clock.³¹

The total amount of delay time is calculated by adding each type of delay together, where appropriate, and subtracting any overlap between the A and B delays.³² Further reductions in delay time apply where an applicant fails to “engage in reasonable efforts to conclude prosecution of the application.”³³ These types of circumstances can occur when an applicant requires additional time beyond the expected 3 months to respond to an office action, filing non-responsive replies, or perhaps when an applicant submits supplemental replies and documents which are not expressly requested by the patent examiner.³⁴

PTA = (PTO Delay A + PTO Delay B + PTO Delay C – Overlap – Applicant’s delay), where PTA ≥ 0³⁵

B. Requests for Continued Examinations Pertaining to B Delays

The central issue of this note and *Mayo Foundation* concerns the calculation of B Delays due to an RCE.³⁶ An RCE allows for continued examination even after the patent examiner has issued an applicant a final rejection.³⁷ The premise behind an RCE is essentially a “do-over”—to start again at the initial office action

³⁰ *Id.*

³¹ *Id.*

³² Norris McLaughlin, *Calculating Patent Term Adjustment (PTA)—An Overview* (Oct. 19, 2018), <https://norrismclaughlin.com/tap/2018/10/19/calculating-patent-term-adjustment-pta-an-overview/>

³³ *Id.*

³⁴ *Id.*

³⁵ Legal Advantage, *A Practical Approach to Calculating Patent Term Adjustment (PTA)* (Oct. 17, 2018) <https://www.legaladvantage.net/blog/a-practical-approach-to-calculate-patent-term-adjustment-pta/>

³⁶ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771 (Fed. Cir. Sept. 16, 2019).

³⁷ Gene Quinn, Michael Benson, *Understanding U.S. Patent Prosecution* (June 30, 2018), <https://www.ipwatchdog.com/2018/06/30/understanding-u-s-patent-prosecution/id=98955/>

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and go through the steps of prosecution again.³⁸ The seminal case of *Novartis AG v. Lee*, held that once an RCE has been filed, there is no B delay available for any time during the continued examination.³⁹ If an RCE was filed during prosecution of an application, applicants are entitled to B delays for the time period between allowance and issuance.⁴⁰

C. Double Patenting

Double patenting prevents the issuance of more than one patent on a claimed invention.⁴¹ There are two types of double patenting issues that the USPTO recognizes: (1) same-invention type and (2) obviousness-type (“OTDP”).⁴² Same-invention type double patenting is a statutory concept stemming from 35 U.S.C. § 101, which states that an inventor “may obtain a patent.”⁴³ On the contrary, OTDP is a non-statutory concept, which occurs when an applicant attempts to claim an invention that is an obvious variant of the original patent.⁴⁴ Thus, the purpose behind rejecting double patents is to prevent a patentee from extending their patent monopoly beyond the statutorily prescribed term.⁴⁵

Although two separate concepts, OTDP and PTAs can become entangled. A prevalent issue arises when two patents share a common priority date because one was filed as a continuation of the other but happen to have different expiration dates due to the PTA.⁴⁶ Recent holdings such as *Novartis AG v. Ezra Ventures, LLC*, and *Mayo Foundation* will affect the future of patent terms and overcoming double patenting rejections.⁴⁷

³⁸ *Id.*

³⁹ *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

⁴⁰ *Id.*

⁴¹ Janice Mueller, *Aspen Student Treatise Series: Patent Law* (5th Edition, 2016).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ Arpita Bchattcharyya, Timothy McAnulty, *CIPA Journal US Update: Double Patenting* (May 2019).

⁴⁷ *Id.*

III. MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH V. IANCU

A. Factual Background

Plaintiff, Mayo, is a Minnesota non-profit corporation and owner of United States Patent No. 8,981,063 ('063 patent).⁴⁸ The '063 patent is related to antibodies that bind to polypeptides, which are useful in treating immunosuppression disease conditions such as cancer, AIDS and other virally or environmentally-induced conditions, and even certain congenital immune deficiencies.⁴⁹ Mayo filed Application No. 12/421,310 ('310 application) on April 9, 2009.⁵⁰ The '063 patent was issued from the '310 application.⁵¹ But on October 14, 2010 the USPTO issued a final office action rejecting all of the claims in the '310 application as anticipated by U.S. Patent No. 7,635,757 ('757 patent), and a few claims for lacking written description.⁵² Come September 14, 2011, Mayo filed an RCE pursuant to 35 U.S.C. 132(b),⁵³ arguing that its application had priority of invention over the '757 patent.⁵⁴ Mayo also filed a supplemental amendment that cancelled some claims which the examiner had noted should be removed as to not interfere in upcoming PTA calculations.⁵⁵ Mayo thus cancelled the claims and pursued them in a continuation application, issued as U.S. Patent 8,460,927 ('927 patent).⁵⁶

⁴⁸ *Mayo Clinic Found. v. Iancu*, 309 F.Supp. 3d 425 (E.D. Va. 2018).

⁴⁹ *Mayo Clinic Found. v. Iancu*, 309 F.Supp. 3d 430 (E.D. Va. 2018).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ 35 U.S.C. § 132(b). Notice of Rejection; Reexamination

“The Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1).”

⁵⁴ *Mayo Clinic Found. v. Iancu*, 309 F.Supp. 3d 430 (E.D. Va. 2018).

⁵⁵ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *7 (Fed. Cir. Sept. 16, 2019).

⁵⁶ *Id.*

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On February 9, 2012, the Administrative Patent Judge issued a declaration of interference⁵⁷ between the remaining claims of the '310 application and all of the claims in the '757 patent.⁵⁸ Finally, two years later on February 19, 2014, the Patent Trial and Appeal Board ("PTAB") awarded the '310 application claims priority and cancelled all of the claims contained in the '757 patent.⁵⁹ The interference was considered final when the period for appeal expired on April 23, 2014.⁶⁰

After the termination of interference, the examiner conducted a further prior art search of the '310 application, which led to the issuance of an Office Action on June 30, 2014 that rejected some claims in the application on grounds of non-statutory obviousness-type double patenting, in light of the '927 patent.⁶¹ The rejections contended that the '927 patent contained claims that had been cancelled in the '310 application.⁶² On October 24, 2014, Mayo filed a reply to the examiner, arguing that the claims contained in the '310 application were patentably distinct from the ones in the '927 patent.⁶³ A notice of allowance was then mailed on November 3, 2014 and finally the '310 application was issued as the '063 patent on March 17, 2015.⁶⁴

The following timeline⁶⁵ provided by Mayo sets forth the dates and prosecution history described above:

⁵⁷ According to the USPTO "An interference is declared to assist the Director of the United States Patent and Trademark Office in determining priority, that is, which party first invented the commonly claimed invention within the meaning of pre-AIA 35 U.S.C. 102(g)(1)."

MPEP § 2301.03 reads:

"An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa."

⁵⁸ *Mayo Clinic Found. v. Iancu*, 309 F.Supp. 3d 430 (E.D. Va. 2018).

⁵⁹ *Id.*

⁶⁰ *Id.*

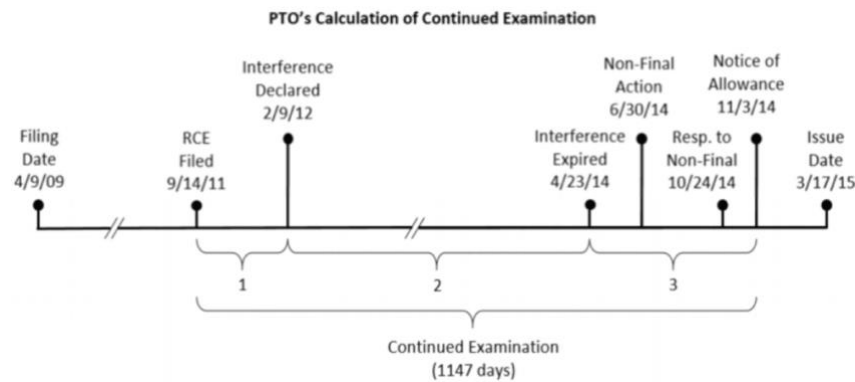
⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Mayo Clinic Found. v. Iancu*, 309 F.Supp. 3d 430 (E.D. Va. 2018).

⁶⁵ Photo indicates prosecution timeframe for the '310 application and '063 patent



Calculation of the Patent Term Adjustment:

Following the issuance of the '063 patent, the USPTO had to calculate the number of PTA days allotted to Mayo.⁶⁶ Although the PTO found both A and C delays, it ultimately determined no B delays attributable to Mayo.⁶⁷ The PTO calculated a total of 621⁶⁸ days of PTA, where Mayo's calculation reflected 685 days.⁶⁹ Mayo's calculation included the PTO's reopening of prosecution after the termination of interference.⁷⁰ This is where the disagreement at suit stemmed. The PTO asserted that continued examination time did not end at termination of interference, but rather at the mailing of the Notice of Allowance.⁷¹

Mayo Foundation for Medical Education & Research v. Iancu., 2019 U.S. App. LEXIS 27771, at *7 (Fed. Cir. Sept. 16, 2019).

⁶⁶ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *7 (Fed. Cir. Sept. 16, 2019).

⁶⁷ *Id.*

⁶⁸ Footnote 1 in *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *7 (Fed. Cir. Sept. 16, 2019) indicates: "Both Mayo and the PTO have since change their PTA calculations...Mayo now claims 723 days, while the PTO has finally determined the Mayo is due 604 days."

Hereinafter, this note will refer to the new PTA calculations.

⁶⁹ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *7 (Fed. Cir. Sept. 16, 2019).

⁷⁰ *Id.* at *7-8.

⁷¹ *Id.* at *8.

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The PTA calculation dispute resulted in Mayo filing for appeal to the United States District Court for the Eastern District of Virginia.⁷² The district court ultimately upheld the PTO's patent term adjustment determination.⁷³ Mayo then appealed to the United States Court of Appeals for the Federal Circuit.⁷⁴ On September 16, 2019, the Federal Circuit affirmed the USPTO and district court's determination for the length of PTA allotted to Mayo.⁷⁵

B. United States Court of Appeals for the Federal Circuit's 2019 Opinion

The Federal Circuit reviewed the district court's grant of summary judgment *de novo*, viewing the evidence in favor of the nonmovant.⁷⁶ The Federal Circuit determined that it must set aside a PTO action only if the decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."⁷⁷ The issue on appeal was one of statutory interpretation, and therefore was also reviewed *de novo*.⁷⁸

i. Statutory interpretation: "request" for examination

On appeal, Mayo set forth its argument based 35 U.S.C. § 154(b)(1)(B)(i), which defines PTA as:

(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

⁷² *Id.* at *1.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *1 (Fed. Cir. Sept. 16, 2019).

⁷⁶ *Id.* at *10.

⁷⁷ *Id.*

⁷⁸ *Id.*

of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application, not including:

- (i) any time consumed by continued examination of the application requested by the applicant under section 132(b).⁷⁹

Mayo contended it never “requested” an examination after the USPTO’s remand, and therefore a post-examination after interference was wrongfully attributed to Mayo’s request.⁸⁰ Mayo read the statute as only allowing declaration of an interference if at least some claims are deemed allowable but for the outcome of the interference.⁸¹ On the other hand, the PTO contended that an interference does not close prosecution on the merits and that its operating procedures contemplate that examination may continue afterward.⁸²

On the first argument, the Federal Circuit agreed with the PTO.⁸³ The Federal Circuit acknowledged Mayo’s idea that the PTO regulations do in fact indicate at least one claim in an application should be in condition for allowance prior to the declaration of an interference.⁸⁴ However, the Federal Circuit noted that the regulations also grant the Board power to recommend any further action by the examiner, including issuing a rejection.⁸⁵ The Court held that collectively, the PTO’s regulations do not indicate that a declaration of interference is equivalent to a Notice of Allowance.⁸⁶

⁷⁹ 35 U.S.C. § 154(b)(1)(B)(i)

⁸⁰ *Mayo Foundation for Medical Education & Research v. Iancu*, 2019 U.S. App. LEXIS 27771, at *11 (Fed. Cir. Sept. 16, 2019).

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.* at *12.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Mayo Foundation for Medical Education & Research v. Iancu*, 2019 U.S. App. LEXIS 27771, at *12 (Fed. Cir. Sept. 16, 2019)

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The Federal Circuit also commented on Mayo's interpretation of the term "requested," stating that 37 C.F.R. § 1.703(b)(1) does not reflect an erroneous interpretation of the statute as Mayo accused.⁸⁷ Rather, the Court believed Mayo placed too much weight on the term, which in fact does not bear much significance at all.⁸⁸

ii. Novartis framework

Looking to the decision in *Novartis v. AG Lee*, Mayo argued that an allowance under 35 U.S.C. § 154(b)(1)(B) is analogous to a declaration of interference.⁸⁹ Mayo contended that claims in a patent are otherwise "deemed allowable" by examiners before interference is declared.⁹⁰ Specifically, Mayo meant that under USPTO regulations, a declaration of an interference comprises an indication of allowability and that examination concludes once the claims are "deemed allowable."⁹¹ Using this framework, Mayo believed that because claims had to be deemed allowable in order to declare an interference, the post-interference proceedings were at the request of the examiner, because Mayo's claims were already allowable prior to interference.⁹²

In response to the *Novartis* argument set forth by Mayo, the PTO claimed prosecution does not close simply due to a declaration of interference and further examination may continue after the fact.⁹³ Using a policy standpoint, the PTO also expressed that if Mayo's argument were allowed, PTA calculations would become "wildly impractical" and "hotly contested factual inquiry in nearly every PTA case."⁹⁴

⁸⁷ *Id.* at *13.

⁸⁸ *Id.* at *13-14.

⁸⁹ *Id.* at *11.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *11 (Fed. Cir. Sept. 16, 2019).

⁹³ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *12 (Fed. Cir. Sept. 16, 2019).

⁹⁴ *Id.*

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Again, the Federal Circuit sided with the PTO.⁹⁵ Citing to its holding in *Novartis*, the Federal Circuit explains “[t]he time between the date of mailing of the Notice of Allowance and the issuance is not RCE time, absent special circumstances where examination is reopened after allowance, because examination of the merits closes upon allowance in the great majority of cases.”⁹⁶ Following the prosecution history, the PTO explained that the examiner for Mayo had the authority to update the prior art search upon remand and issue a rejection as it saw fit.⁹⁷ Mayo then succeeded in its response to the examiner, which then secured allowance—not prior to interference as Mayo believes.⁹⁸ However, the Court explains that following this timeline, it shows that examination ended once the Notice of Allowance was mailed—not at the expiration of interference.⁹⁹

iii. Holding

The Federal Circuit affirmed the decision of the district court, holding the USPTO correctly determined there was no B Delay to be granted to Mayo.¹⁰⁰

C. Dissent

In a dissent by Judge Newman, he stated his disagreement with the majority’s holding that post-interference examination period is not included in the patent term adjustment.¹⁰¹ Newman’s reasoning is reflected in his belief that the majority’s holding does

⁹⁵ *Id* at *12-13.

⁹⁶ *Id* at *13.

⁹⁷ *Id*.

⁹⁸ *Id* at *14.

⁹⁹ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *13 (Fed. Cir. Sept. 16, 2019).

¹⁰⁰ *Id* at *16.

¹⁰¹ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *17 (Fed. Cir. Sept. 16, 2019) (Newman, C.J., dissenting).

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not align with the statutory provisions and precedent regarding PTAs.¹⁰²

The dissent disagreed with the majority's use of 37 C.F.R. § 1.703(b)(1) as limiting the patent term adjustment after continued examination was requested.¹⁰³ In agreement with Mayo's argument, the dissent read that § 1.703(b)(1) "was adopted to establish that the period of examination ends with mailing of the notice of allowance; it has no relation to post-interference examination."¹⁰⁴

The dissent argued the application of *Novartis* was erroneous, as the case did not relate to prosecution or activity prior to the Notice of Allowance.¹⁰⁵ Rather, *Novartis* was "concerned only with the 'time from allowance to issuance.'"¹⁰⁶ Newman stated there was no dispute to whether the PTO had authority to reopen examination after the termination of interference; citing to MPEP § 2308¹⁰⁷, further examination, when there is no recommendation in the interference judgment, is at the initiative of the examiner.¹⁰⁸

Finally, the dissent pointed to Congressional intent of term adjustments. The intentions behind PTAs are to penalize only those who purposely manipulate the system, which does not apply in Mayo's case.¹⁰⁹ In terms of purpose, § 1.703(b)(1) requires

¹⁰² *Id.*

¹⁰³ *Id.* at *19.

¹⁰⁴ *Id.*

¹⁰⁵ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *21 (Fed. Cir. Sept. 16, 2019) (Newman, C.J., dissenting).

¹⁰⁶ *Id.*

¹⁰⁷ MPEP § 2308

"If there is no recommendation in the judgment, the examiner should update the search and may, but is not required to, reopen prosecution for any claim not disposed of in the judgment. An interference judgment simply resolves any question of priority between the two parties to the interference. The judgment does not prevent the examiner from making a rejection in further examination in the same application or a different application."

¹⁰⁸ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *22 (Fed. Cir. Sept. 16, 2019) (Newman, C.J., dissenting).

¹⁰⁹ *Id.* at *24.

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examination delay to be requested by the applicant, which is also not the case for Mayo.¹¹⁰ Therefore, the interference delay should be part of the adjustment calculations.¹¹¹

IV. ANALYSIS

A. Statutory Interpretation

Mayo argues that the court's reading of 37 C.F.R. § 1.703(b)(1) misrepresents the meaning of RCE, as it is defined in the statute.¹¹² Where 35 U.S.C. § 154(b)(1)(B)(i) states that time consumed by continued examination requested by the applicant is not included in PTA time, Mayo argues that it did not "request" examination following the Board's remand.¹¹³ 37 C.F.R. § 41.127(c) states that an interference judgment may include recommendations for further action by the examiner or the Board, and if the Board recommends rejection of a claim of an involved application, the examiner "must enter and maintain the recommended rejection..."¹¹⁴ Mayo's interference proceedings did not contain any further recommendation actions by the Board.¹¹⁵ The dissent used MPEP § 2308¹¹⁶ for guidance on when there is no further recommendations to be taken.¹¹⁷ In such instances, the "examiner should update the search and may, but is not required to, reopen prosecution for any claim not disposed of in the judgment."¹¹⁸ Moreover, § 2308 interprets an interference as solving questions of priority between two parties; it does not prevent

¹¹⁰ *Id.*

¹¹¹ *Id.* at *24-25.

¹¹² *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *22 (Fed. Cir. Sept. 16, 2019) (Newman, C.J., dissenting).

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ See *supra* note 97.

¹¹⁷ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *22 (Fed. Cir. Sept. 16, 2019) (Newman, C.J., dissenting).

¹¹⁸ *Id.*

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an examiner from making rejections in further examination of the same application.¹¹⁹

Using the MPEP as guidance, since no recommendation for further action was provided by the examiner during the interference, the language makes clear that the examiner should update the search but “[i]s not required to, reopen prosecution.”¹²⁰ The decision to make further examinations is clearly given to the examiner.¹²¹ Although Mayo requested the initial RCE, it did not ask for continued examination after the termination of interference.¹²² Rather, the examiner chose to further examine the claim language of the ‘310 application for obviousness-type double patenting.¹²³ The majority made the argument that because Mayo made the initial request and that prosecution does not end until the mailing of the notice of allowance, that all time after interference is part of the RCE time and will not be allotted any PTA.¹²⁴ Through this framework, the majority seems to believe that RCE is all encompassing and even includes examination of aspects that the applicant did not specifically ask for. The code of federal regulations and MPEP plainly set out the road map that post interference examination is a decision attributed to the examiner and is not encompassed in a continued examination request by the applicant.¹²⁵

B. Application of Novartis

Both parties make strong arguments regarding when a claim is “deemed allowable” based on the holding of *Novartis*. The premise of *Novartis* was that examination ends at the notice of allowance rather than the issue date of a patent.¹²⁶ The *Novartis*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.* at *23.

¹²³ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *23 (Fed. Cir. Sept. 16, 2019) (Newman, C.J., dissenting).

¹²⁴ *Id.*

¹²⁵ *Id.* at *22-23.

¹²⁶ *Id.* at *21.

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conclusion only settles the question in so far as disregarding time between the notice of allowance and the date of issuance, which is not at dispute in *Mayo Foundation*.¹²⁷ As the majority also states in *Mayo Foundation* regarding *Novartis*, “[e]xamination as used in § 154(b)(1)(B) ‘presumptively ends at allowance, when prosecution is closed and there is no further examination on the merits in the absence of a special reopening.’”¹²⁸ The majority’s reading of the *Novartis* case is correct. *Novartis* was concerned with when prosecution ends; it is clear that prosecution ends at the notice of allowance instead of the issue date.¹²⁹ After a notice of allowance there are no longer any prosecution steps by the examiner; control of the patent leaves the hands of the examiner and goes into the hands of the publisher—therefore, it is presumed that prosecution ends at the notice of allowance.¹³⁰ *But* it is important to consider, as the dissent points out, the case at hand is not regarding when prosecution ends.¹³¹ Rather, *Mayo Foundation* concerns when prosecution time attributed to fault of the applicant ends.¹³² Specifically, the case at hand asks if post interference examination is a continuation of RCE at the expense of the applicant, or if it is a separate examination at the hands of the examiner.¹³³ Although the reading of *Novartis* is correct, it is not correct in terms of Mayo’s issues. The dissent correctly argues that *Novartis* is not applicable in Mayo’s case because it was merely concerned with establishing the meaning of the time between the mailing of the Notice of Allowance and the issuance of the patent.¹³⁴

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

¹³⁰ Changes to Patent Term Adjustment in view of the Federal Circuit Decision in *Novartis v. Lee*, 80 Fed. Reg. 1346,

<https://www.federalregister.gov/documents/2015/01/09/2015-00061/changes-to-patent-term-adjustment-in-view-of-the-federal-circuit-decision-in-novartis-v-lee>

¹³¹ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *21 (Fed. Cir. Sept. 16, 2019) (Newman, C.J., dissenting).

¹³² *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771 (Fed. Cir. Sept. 16, 2019).

¹³³ *Id.*

¹³⁴ *Id.* at *21.

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C. Did the majority get it right?

The majority's firm opinion seems flawed. If the purpose of patent term adjustments is to compensate the patentee for delay caused by the USPTO during prosecution, then it should do so wholly. The dispute in *Mayo Foundation* is over 112 days-, yet the time taken to appeal the case took well over 100 days.¹³⁵ PTA is compensated to patentees so long as there is no sense of misleading or deceiving the patent office.¹³⁶ It was not disputed that Mayo did not try to deceive the patent office.¹³⁷ During prosecution Mayo played by the rules and did just as the examiner asked every step of the way.¹³⁸ It is counterintuitive, in light of the purpose behind obtaining a patent, for PTAs to penalize an applicant for abiding by the requests of the examiner but not being properly compensated for their efforts.

Matters of this sort should be saved for the court in cases where a patentee is clearly attempting to take advantage of the patent office and term adjustments to their patent. In cases where no such deceit is in dispute, it would be better for the examiners, patent office, and courts to spend their time consulting issues of greater importance. Judgments such as the one the majority made here will only add reasons to dissuade people from applying for patents—the complete opposite of the intent for patents.¹³⁹

¹³⁵ Footnote 1 in *Mayo Foundation for Medical Education & Research v. Iancu*, 2019 U.S. App. LEXIS 27771, at *7 (Fed. Cir. Sept. 16, 2019) indicates: “Both Mayo and the PTO have since change their PTA calculations...Mayo now claims 723 days, while the PTO has finally determined the Mayo is due 604 days.”

¹³⁶ *Mayo Foundation for Medical Education & Research v. Iancu*, 2019 U.S. App. LEXIS 27771, at *24 (Fed. Cir. Sept. 16, 2019)(Newman, C.J., dissenting)(citing H.R. Rep. No. 106-287, pt. 1, at 49-50 (1999)).

¹³⁷ *Mayo Foundation for Medical Education & Research v. Iancu*, 2019 U.S. App. LEXIS 27771, at *24 (Fed. Cir. Sept. 16, 2019) (Newman, C.J., dissenting).

¹³⁸ *Id* at *24.

¹³⁹ Joe Hadzima, Boston Business Journal, *The Importance of Patents: It Pays to Know Patent Rules*, <http://web.mit.edu/e-club/hadzima/the-importance-of-patents.html>

V. IMPLICATIONS OF MAYO ON DOUBLE PATENTING

The primary focus of *Mayo Foundation* is the discrepancy of days calculated between Mayo and the PTO regarding delay time allotted for the patent term adjustment.¹⁴⁰ Although the outcome of the case is focused on calculation of PTA days, the holding can have greater implications on patents, specifically regarding obviousness-type double patenting.

The Federal Circuit's recent decision in *Novartis Pharms. Corp. v. Ezra Ventures LLC*, shows how obviousness-type double patenting is affected by Patent Term Extensions ("PTE").¹⁴¹ *Ezra* narrows the reach of OTDP by holding a PTE is valid "as long as the extended patent is otherwise valid without the extension."¹⁴² The Novartis patent was granted PTE time due to FDA delays during the drug approval process.¹⁴³ Novartis filed for infringement when Ezra attempted to market a generic version of the patented drug.¹⁴⁴ The PTE for Novartis extended the patent's term beyond that of a later-filed patent claiming the treatment methods of using the drug's active ingredients.¹⁴⁵ In defense, Ezra claimed that OTDP cuts Novartis' PTE time.¹⁴⁶ The Court ultimately held that OTDP is a "judge-made doctrine" whose purpose is to prevent PTE beyond a statutory time limit.¹⁴⁷ Since PTE is a statutorily defined concept,

¹⁴⁰ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771 (Fed. Cir. Sept. 16, 2019).

¹⁴¹ *Novartis Pharms. Corp. v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018).

¹⁴² Jo Dale Carothers, The IP Blog, *Federal Circuit Narrows Reach of Obviousness-Type Double Patenting* (Dec. 20, 2018) <https://www.theiplawblog.com/2018/12/articles/patent-law/federal-circuit-narrows-reach-of-obviousness-type-double-patenting/>

¹⁴³ Payal Majumdar, *Obviousness-Type Double Patenting Does Not Invalidate Patent Term Extensions* (Feb. 1, 2019) <https://oshaliang.com/uncategorized/obviousness-type-double-patenting-does-not-invalidate-patent-term-extensions/>

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

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allowing OTDP to curtail PTE would be beyond the scope of purpose for obviousness-type double patenting.¹⁴⁸

Without prior knowledge or context, it is easy to assume that a patent term adjustment is equivalent to a patent term extension. The concepts are similar—they add additional time to the life of a patent that has been otherwise consumed by the prosecution process.¹⁴⁹ A PTE is defined by 35 U.S.C. § 156 and is applicable when the patent applicant is responsible for prosecution delays.¹⁵⁰ On the contrary, a PTA is appropriate when an application has been delayed because of the USPTO.¹⁵¹

Through cases like *Ezra*, and other recent decisions such as *Gilead Sciences, Inc. v Natco Pharma Ltd.*,¹⁵² the Federal Circuit has opened the scope of PTEs so that obviousness-type double patenting is not able to interfere with the life of a patent. However, courts have yet to determine how OTDP plays a role in cases with patent term adjustments rather than extensions. The basis of *Ezra* is that OTDP is a judge-made doctrine aimed at preventing a patent's span beyond its "statutorily afforded term."¹⁵³ Since PTE is a

¹⁴⁸ Arpita Bchattcharyya, Timothy McAnulty, CIPA Journal *Double Patenting* (Jan. 2017).

¹⁴⁹ Thomas L. Irving, Jill K. MacAlpine, Charles E. Van Horn, Patent Term Adjustments and Extensions: Leveraging Recent Decisions and USPTO Rule Changes (Oct. 11, 2018). <http://media.straaffordpub.com/products/patent-term-adjustments-and-extensions-leveraging-recent-decisions-and-uspto-rule-changes-2018-10-11/presentation.pdf>

¹⁵⁰ 35 U.S.C. § 156.

(a)The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—

¹⁵¹ Thomas L. Irving, Jill K. MacAlpine, Charles E. Van Horn, Patent Term Adjustments and Extensions: Leveraging Recent Decisions and USPTO Rule Changes (Oct. 11, 2018). <http://media.straaffordpub.com/products/patent-term-adjustments-and-extensions-leveraging-recent-decisions-and-uspto-rule-changes-2018-10-11/presentation.pdf>

¹⁵² *Gilead Sciences, Inc. v Natco Pharma Ltd.*, 753 F.3d 1208, 1215 (Fed. Cir. 2014).

¹⁵³ *Novartis Pharms. Corp. v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018).

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statutory concept, it therefore cannot be invalidated using OTDP.¹⁵⁴ On the same note, it could be presumed that future case holdings regarding PTAs will align with the *Ezra* outcome as well. If future courts stay in line with *Ezra*, the idea of OTDP will immensely change patent law. From the perspective of a patent applicant, they will be afforded greater protection and longer rights to their family of patents, by being able to claim virtually the same claims with just a few slight changes, to extend the life of that patent. On the flipside, applying the *Ezra* reasoning works against the purpose of having a patent: establishing a 20 year monopoly but then allowing the rest of the market a chance to benefit off the claimed ideas and concepts.¹⁵⁵ The narrowing framework of disallowing OTDP to curtail a statutory adjustment is beneficial to the patent applicants and potentially very harmful to future American innovators.

The statutory language of section 156 states that the term of the patent “shall be extended...from the original expiration date of the patent, *which shall include any patent term adjustment granted under section 154(b)...*”¹⁵⁶ (emphasis added). A literal reading of the statute indicates that a patent term adjustment is included in a patent term extension. Although the issue of ODTP has not been addressed in courts as it pertains to PTAs, it could be implied through section 156 that because PTAs are included in PTE calculations—and PTAs are also a statutory doctrine—that their treatment in regards to ODTP should resemble that of PTEs. In *Gilead*, the court held that the expiration date of the patents should be looked at to determine an ODTP reference and how to overcome it.¹⁵⁷ If a PTA is thus treated like a PTE in regard to double patenting rejections, this means that an applicant will be allotted the additional PTA days owed by the USPTO regardless. Applying the limiting ODTP results from *Ezra*, an application requiring PTA will be able to continue its life without worrying about a non-statutory double patenting rejection.

¹⁵⁴ *Id.*

¹⁵⁵ James Yang, OC Patent Lawyer *Purpose of the patent system* (April 11, 2018) <https://ocpatentlawyer.com/lesson/purpose-benefits-patent-system/>

¹⁵⁶ See *supra* note 139.

¹⁵⁷ *Gilead Sciences, Inc. v Natco Pharma Ltd.*, 753 F.3d 1208, 1215 (Fed. Cir. 2014).

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Since cases of PTAs and obviousness-type double patenting have not been litigated, it is still up in the air as to how a court would rule on this type of matter.¹⁵⁸ A court could treat it like *Ezra* and *Gilead*, such as the scenario described above. On the other hand, a court could also decide to not apply the narrowing scope of *Ezra* to PTAs and instead keep it only to PTEs.

VI. CONCLUSION

The holding in *Mayo Foundation* conveys that if an interference was declared during prosecution, even without the request of the applicant, the applicant is responsible for the delay time.¹⁵⁹ The outcome of *Mayo Foundation* penalizes applicants for the prosecution process in which interference was due to the examiner. Although the majority explained the *Novartis* case correctly, it failed to properly apply the case to the matter at hand. The question surrounding *Novartis* was profoundly different than the one faced in *Mayo Foundation*.¹⁶⁰ While *Novartis* focused on the expiration of a patent at either the notice of allowance or date of issuance, *Mayo Foundation*'s question relied on the determination of post interference delay and who (applicant or examiner) is responsible for the delay.¹⁶¹ The dissent correctly argued that the post interference delay in *Mayo Foundation* was at the fault of the examiner and not Mayo. The examiner had the right to open examination after the expiration of interference but was not required to do so.¹⁶² Thus, it only seems logical that the post interference

¹⁵⁸ Payal Majumdar, *Obviousness-Type Double Patenting Does Not Invalidate Patent Term Extensions* (Feb. 1, 2019)

<https://oshaliang.com/uncategorized/obviousness-type-double-patenting-does-not-invalidate-patent-term-extensions/>

¹⁵⁹ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771 (Fed. Cir. Sept. 16, 2019).

¹⁶⁰ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *21 (Fed. Cir. Sept. 16, 2019) (Newman, C.J., dissenting).

¹⁶¹ *Mayo Foundation for Medical Education & Research v. Iancu.*, 2019 U.S. App. LEXIS 27771, at *21 (Fed. Cir. Sept. 16, 2019) (Newman, C.J., dissenting).

¹⁶² *Id.*

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proceedings were at the discretion of the examiner. Mayo followed all the steps requested by the examiner, and at no point attempted to deceive the patent office.¹⁶³ Yet, in the end, was punished for following the rules.¹⁶⁴ The majority's opinion shifts focus from the purpose of granting patents and instead places additional roadblocks in front of applicants.

The dispute over a few months delay seems trivial in light of the fact that patents have a 20-year life span. Although the Mayo PTA dispute did not involve a significant amount of time, each day is crucial for the patent applicant. The lifespan of a patent can affect other patents within the family of patents.¹⁶⁵ Regarding OTDP, there have been no cases that rule on PTAs.¹⁶⁶ However, if courts take the same approach to OTDP in patent term adjustments, as they did for patent term extensions in *Novartis v. Ezra*, it becomes crucial to properly calculate the delay days returned to the patent. If, however, a court does not apply the *Ezra* reasoning associated with PTEs to PTA circumstances, such as what is presented in *Mayo Foundation*, there will still be implications. Obtaining a patent is already a cumbersome and timely process.¹⁶⁷ The additional challenge of worrying over lost time caused by the examiner, but taken at the expense of the applicant, only hinders the process and purpose of obtaining a patent. The overall purpose of obtaining an exclusive right is to promote innovation.¹⁶⁸ This purpose cannot be upheld if the focus of courts remains on such small matters between an applicant and the examiner. Depending on the patent's timeline, it can either give more power to the patentee or take away power

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ Elizabeth A. Doherty, Amelia Feulner Baur, *Navigating through the Obviousness-Type Double Patenting Minefield* (Jan. 2018).

¹⁶⁶ Payal Majumdar, *Obviousness-Type Double Patenting Does Not Invalidate Patent Term Extensions* (Feb. 1, 2019)

<https://oshaliang.com/uncategorized/obviousness-type-double-patenting-does-not-invalidate-patent-term-extensions/>

¹⁶⁷ IP Spotlight: *How long does it take to get a patent or trademark? (2018 Update)* (Jan 11, 2019), <https://www.jdsupra.com/legalnews/how-long-does-it-take-to-get-a-patent-21821/>

¹⁶⁸ James Yang, OC Patent Lawyer *Purpose of the patent system* (April 11, 2018) <https://ocpatentlawyer.com/lesson/purpose-benefits-patent-system/>

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from the patentee, to protect related patents within the family and withstand an OTDP reference.