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EXECUTIVE SERIES:
INTELLECTUAL PROPERTY

After *Cellect* and *Allergan*: Patent Prosecution and Litigation Strategies in View of Recent Obviousness-Type Double Patenting (OTDP) Decisions

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The Prohibition Against Obviousness-Type Double Patenting

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Obviousness-type double patenting (OTDP): Why does it exist & When does it apply?

- Two-century-old doctrine
- Originally, patent terms ran 14 years from **issuance**
- **Problem:** If a continuation issues with similar or identical claims, continuation would effectively extend original patent's term
  - solution: prohibition against Double Patenting
  - see *Barrett v. Hall,* 2 F. Cas 914, 924 (C.C.D. Mass 1818): an inventor cannot "have in use at the same time two valid patents for the same invention"

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Double patenting: Two distinct types

- **"Statutory" double patenting:**

  prohibits obtaining claims having "*identical subject matter*" to another of patentee's patents. 35 U.S.C. § 101 ("[w]hoever invents … may obtain ***a*** patent …")
  - applies to claims with **identical** scope
  - must be addressed using claim cancelation or amendment

- **"Obviousness-type" double patenting:**

  prohibits claims that "*would have been obvious* from … the claims in the first patent"

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Obviousness-type double patenting

- Judicially created doctrine grounded in **public policy** rather than based purely on precise terms of the statute.
- See Manual Patent Examining Procedure Sec. 804
  - "The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that:
  - *The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent."*

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Obviousness-type double patenting

- OTDP differs from the "standard" obviousness analysis under § 103 analysis in key aspects:
  - "standard" obviousness analysis: reference application/patent has to qualify as prior art under § 102/§ 103 analysis.
  - OTPD analysis: reference application/patent does **not** have to qualify as prior art under § 102/§ 103 analysis:
    - publication date of reference application/patent may be irrelevant
  - OTPD analysis: focus is on the claims of the reference application/patent. The specification of the reference application/patent cannot be considered except for the purpose of construing a claim.

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Obviousness-type double patenting: Exceptions

- Patents filed separately from one another at the behest of the Patent Office (Restriction Requirement or equivalent): **divisionals**

35 U.S.C. § 121: "… *A patent issuing on an application with respect to which a requirement for restriction under this section has been made […] shall not be used as a reference either in the Patent and Trademark Office or in the courts against a* ***divisional*** *application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. …*"

  - § 121 safe harbor does **not** apply to continuations or continuations-in-part

- Filing a **Terminal Disclaimer (TD)** renouncing any portion of the successor's term that outlasts the first patent

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Terminal disclaimers

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT

- The owner, ____, of ____ percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent No. [reference patent] as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.
- In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: expires for failure to pay a maintenance fee; is held unenforceable; is found invalid by a court of competent jurisdiction; is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; has all claims canceled by a reexamination certificate; is reissued; or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

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Terminal disclaimers

TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION

- The applicant ____, owner of ____ percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number [reference application], filed ____, as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.
- In making the above disclaimer, the applicant does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that: any such patent granted on the pending reference application expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

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Overcoming obviousness-type double patenting

- File terminal disclaimer, provided that:
  - reference application/patent is shown to be **commonly owned** with application in question [37 C.F.R. § 1.321(c)], or
  - claims an invention made as result of activities undertaken within scope of **joint research agreement** [37 C.F.R. § 1.321(d)]
  - **note:** TD apply to **all claims in patent**, not only those rejected by OTDP
- Amend and/or cancel rejected claims of application in question
- Argue against rejection:
  - arguments similar to "standard" obviousness rejection, except focus is on **claims** of reference application/patent

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How a U.S. patent can exceed 20 years of patent term

- The term of a U.S. patent runs 20 years from **earliest filed non-provisional application date** (PCT or U.S. non-provisional)
- **Exceptions:**
  - Patent Term Adjustment (PTA) for delays in USPTO action during prosecution: 35 U.S.C. § 154(b)
    - PTA is commonly observed in U.S. prosecution
  - Patent Term Extensions (PTE) for drugs & medical devices patent to compensate for delays in FDA approval: 35 U.S.C. § 156
    - PTE is limited to inventions associated with FDA approval

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But what is Patent Term Adjustment ("PTA") ?!?

- PTA was established by the American Inventors Protection Act of 1999 and codified at 35 USC § 154(b)
- This should be distinguished from:
  - old regime of PTA, which applied to patents issuing on applications filed on or after June 8, 1995, but before May 29, 2000; and
  - Patent Term Extension codified at 35 USC § 156 to compensate for delays associated with approval by the Food and Drug Administration ("FDA")

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Why was PTA established?

- Prior to 1995, US patents were entitled to a patent term of 17 years from issue
- In 1995, the US changed to the patent term to 20 years from the earliest effective US non-provisional filing date to implement the TRIPS Agreement
- Under a 17-years-from-issue term, examination delays do not diminish the patent term
- Under a 20-years-from-earliest-effective-filing-date term, examination delays erode the effective patent term:
  - if examination takes 3 years, the patent can be enforced for 17 years
  - if examination takes 5 years, the patent can be enforced for 15 years

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PTA is very important for portfolio management

- PTA lengthens a patent's term beyond 20 years
- This can be extremely valuable for products that have long regulatory and/or development approval lifecycles:
  - pharmaceuticals
  - medical devices
  - university-licensed technologies
- A "blockbuster drug" is a drug that generates at least $1 Billion in annual revenue
- $1Billion/365 days of revenue ≈ $2.7Million/day of revenue

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Compact prosecution

- What is "Compact Prosecution"?*
  - conducting an initial search which is as complete as possible;
  - citing pertinent art on the record in keeping with the scope of the claims as well as significant aspects of the disclosed invention;
  - issuing a complete first Office action which clearly explains the Examiner's position on each essential issue; and
  - identifying allowable subject matter in an effort to expedite prosecution.
- PTA law and rules generally reflect compact prosecution principles

* USPTO, "Best Practices in Compact Prosecution: Awareness Workshop," http://www.uspto.gov/patents/law/exam/compact_prosecution.pdf.

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Patent term adjustment statutory scheme

Three types of delays:

- "A Delays": 35 USC § 154(b)(1)(A), adjustment for administrative delays for:
  - issuing Office Action
  - respond to a reply or appeal
  - acting on application after decision from Board of Patent Appeals and Interferences or Federal Court
  - Issuing patent after payment of issue fee
- "B Delays": 35 USC § 154(b)(1)(B), guarantee of no more than 3-year application pendency (except RCEs and Appeals)
- "C Delays": 35 USC § 154(b)(1)(C), adjustment for interferences and derivation proceedings, secrecy orders, and successful appellate review

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Patent term adjustment statutory scheme

- Limitations on PTA:
  - double-counting prohibited
  - adjusted term may not extend beyond expiration date specified in terminal disclaimer
  - reductions in PTA for applicant delays
- Procedures for determining and correcting PTA: attention needed after patent issues!
- **Make sure to check PTA calculations once patent issues!**

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In re Cellect LLC, 81 F.4th 1216 (Fed. Cir. 2023)

Backdrop

- Switch to 20-year term from filing of application (Uruguay Round Agreements) created new question: can an earlier-issued patent be invalidated by later-issued (and perhaps even later-filed) patent?
- Question remained after *In re Cellect*

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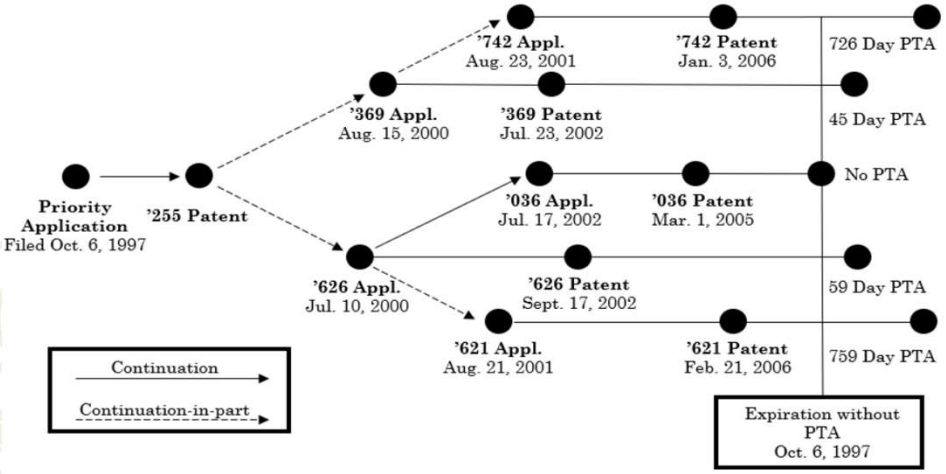
In re Cellect LLC, 81 F.4th 1216 (Fed. Cir. 2023)



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In re Cellect LLC, 81 F.4th 1216 (Fed. Cir. 2023)

- Four Cellect patents granted PTA under 35 U.S.C. § 154
- Earlier issued Cellect patents used as basis of the Obviousness-Type Double Patenting rejections, all of which claimed same effective filing date as rejected patents
  - but for PTA, all patents would have had identical expiration date
  - previously issued patent had not had terms adjusted so terms ended before the terms of the rejected patents
  - **all four rejected Cellect patents were invalidated because of Patent Office delays during original examination period**

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In re Cellect LLC, 81 F.4th 1216 (Fed. Cir. 2023)

- Cellect patents granted PTA under 35 U.S.C. § 154:
  - *In re Cellect:* differences in patent term extensions between patent family members can render the patent with the longer term unenforceable, even where the term extension is due to Patent Office delays.

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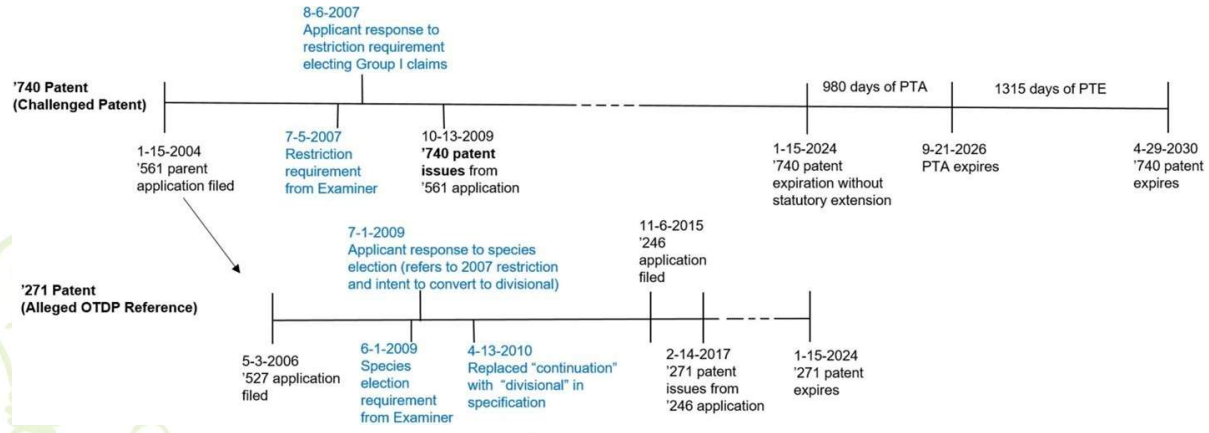
Post-*In re Cellect*:
Acadia Pharm. Inc. v. Aurobindo Pharm. Ltd., C. A. No. 20-985-GBW, 2023 WL 8803448 (D. Del. Dec. 13, 2023)



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Post-*In re Cellect*:
Acadia Pharm. Inc. v. Aurobindo Pharm. Ltd., C. A. No. 20-985-GBW, 2023 WL 8803448 (D. Del. Dec. 13, 2023)

- Judge Williams denied summary judgment of invalidity for OTDP:
  - *"The Court has been unable to identify a case where, when challenged, a later-filed, later-issued, earlier-expiring patent was used as an OTDP reference to invalidate an earlier-filed, earlier-issued, later-expiring patent. Here, the claims in the challenged patent were earlier filed and thus are entitled to their full term, including the PTA."*
  - reference '271 patent was "filed as a result of" a restriction requirement, thus safe harbor applied to protect '740 patent.
  - '271 patent not proper reference against '740 patent

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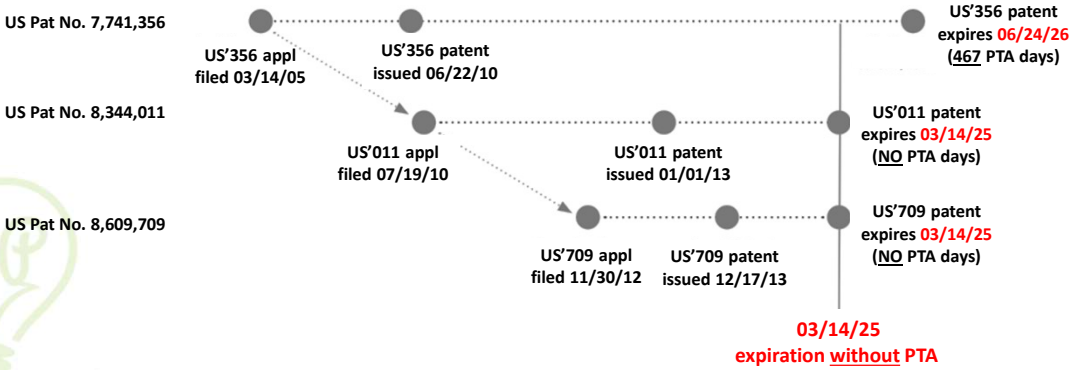
Post-*In re Cellect*:
Allergan USA, Inc. v. MSN Labs., 111 F.4th 1358 (Fed. Cir. 2024) (reversing SJ of invalidity for OTDP)



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Post-*In re Cellect*:
Allergan USA, Inc. v. MSN Labs., 111 F.4th 1358 (Fed. Cir. 2024) (reversing SJ of invalidity for OTDP)

- First-filed, first-issued, later-expiring patent claim **not** invalid for OTDP over later-filed, later-issued, earlier-expiring patents sharing priority
  - *"Our holding in Cellect is only controlling in this case to the extent that it requires us to consider, in our ODP analysis, the [first patent's] June 24, 2026 expiration date (i.e., the expiration date after the addition of PTA), not the March 14, 2025 expiration date that it would have shared with [later-filed, later-issued continuations] reference patents simply because it expires later."*

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REAL WORLD EXAMPLE:
Lindis Biotech GmbH v. Amgen Inc., No. 22-35-GBW (D. Del.)

'421 Patent

Filed Oct. 26, 2007

Issued Apr. 29, 2014

Expires Mar. 4, 2028

PTA: 1,042 days

Terminal Disc. Apr. 3, 2018

Claims priority to Apr, 26, 2005 priority application

Filed Apr. 7, 2014, CIP of '421 Patent

Issued Sep. 11, 2018

Expires Apr. 26, 2025

'158 Patent

PTA: 0 days

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Prosecution considerations for portfolio management in view of TD/OTDP concerns

- Strategizing portfolio set-up:
  - single comprehensive patent family vs. multiple future overlapping patent families
  - § 121 divisional safe harbor protection vs. extended patent expiration dates
- Multiple overlapping patent families: should you take a TD?
- TD filing is not the only response to an OTDP rejection:
  - amend rejected claim, cancel rejected claim, argue against rejection
- Review complex portfolios before first expiration in family(ies)
- Could trigger divisionals in each filing (extend safe harbor protection, if possible)
- Could be aggressive with most valuable/broadest subject matter in parent, and then walk divisionals more slowly (*Allergan)*

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