

**2nd BCLT
Advanced Life Sciences Institute**

**Obviousness-Type Double
Patenting Post-*Cellest*:
Strategies and Best Practices**

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Agenda

- **ODP Challenge**
- **Timing Considerations of ODP**
 - PTE v. PTA
- **Latest Court Guidance**
 - *In re Collect*
 - *Post-In re Collect*
- **Litigation Considerations**
 - Using ODP as Defendant
 - Addressing ODP as Plaintiff
- **Mitigating ODP during Prosecution**
 - ODP rejections and responses
 - Maximizing Safe harbor protection

ODP Challenge

- **What:** Obviousness-Type Double Patenting (ODP)
Judicial doctrine that pits patentee's own patents against one another.
- **How:** Instead of invalidating patentee's claims over prior art (or for other shortcomings), ODP challenger argues patentee got two (or more) patents with claims to *essentially the same thing* (obvious variants), so patentee is improperly extending its patent term.
- **Result:** If ODP is found, challenged patent is **invalid**.
- **When:** Disputed claims have **different** expiration dates.

Why Are There Different Expiration Dates?

Patent Term Extension

- 35 U.S.C. § 156
- Compensates for **regulatory delays** (up to 5 years and not 14 years from approval).
- Responsibility of determining PTE shared by USPTO and FDA, but applicant may request reconsideration.

Patent Term Adjustment

- 35 U.S.C. § 154
- Compensates for undue **delay by PTO** during patent prosecution.
- USPTO determines PTA, but applicant may request reconsideration.

Patents with the same priority date can have different expiration dates.

ODP – Which Expiration Date to Use?

Patent Term Extension

- Expiration date **before** the PTE has been added
- *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007); *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018).

Patent Term Adjustment

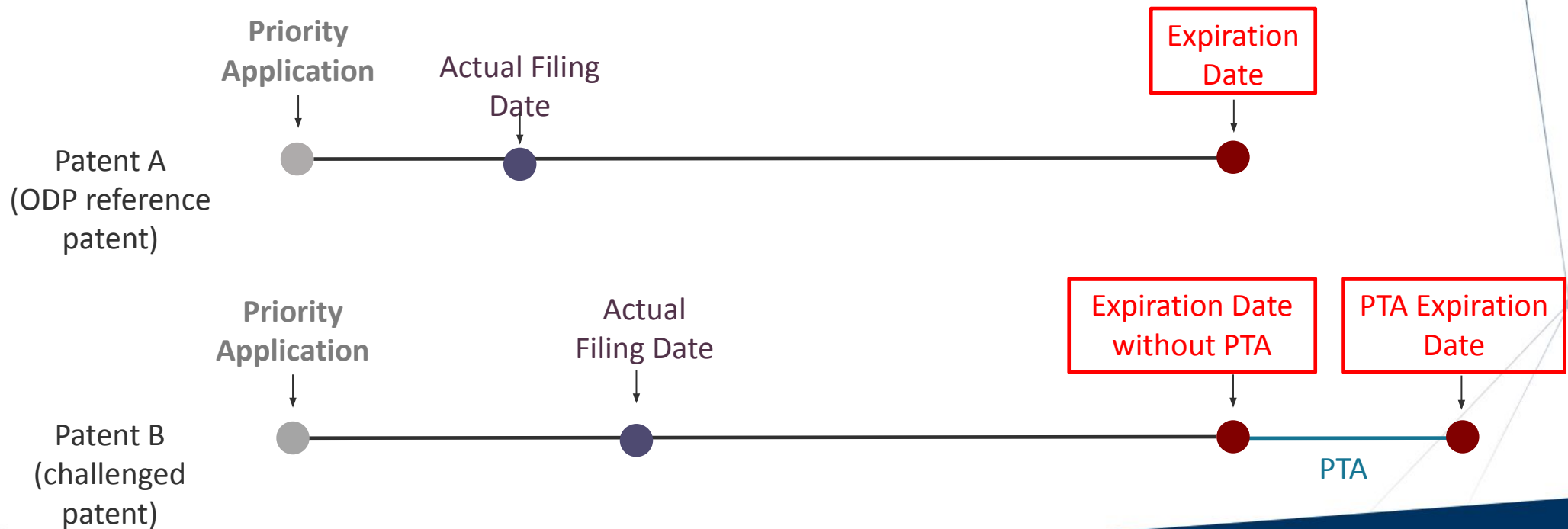
- Was unclear—maybe **before** the PTA has been added or **after** the PTA has been added.

Patents with the same priority date can have different expiration dates.

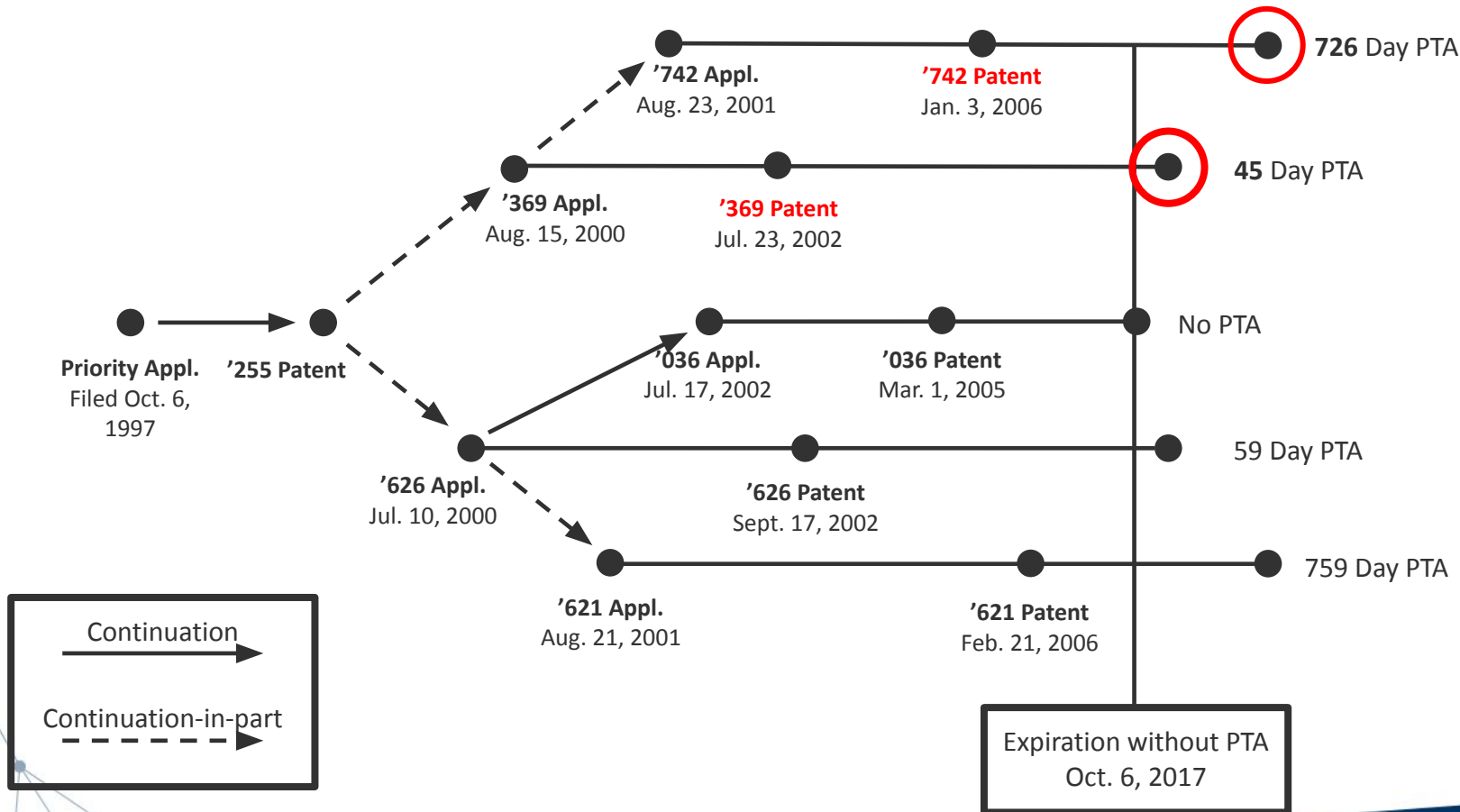
***In re Collect, LLC*, 81 F.4th 1216 (Fed. Cir. 2023).**

In re Collect:

Is ODP based on the date of expiration of a patent that includes PTA pursuant to 35 U.S.C. § 154, or not?

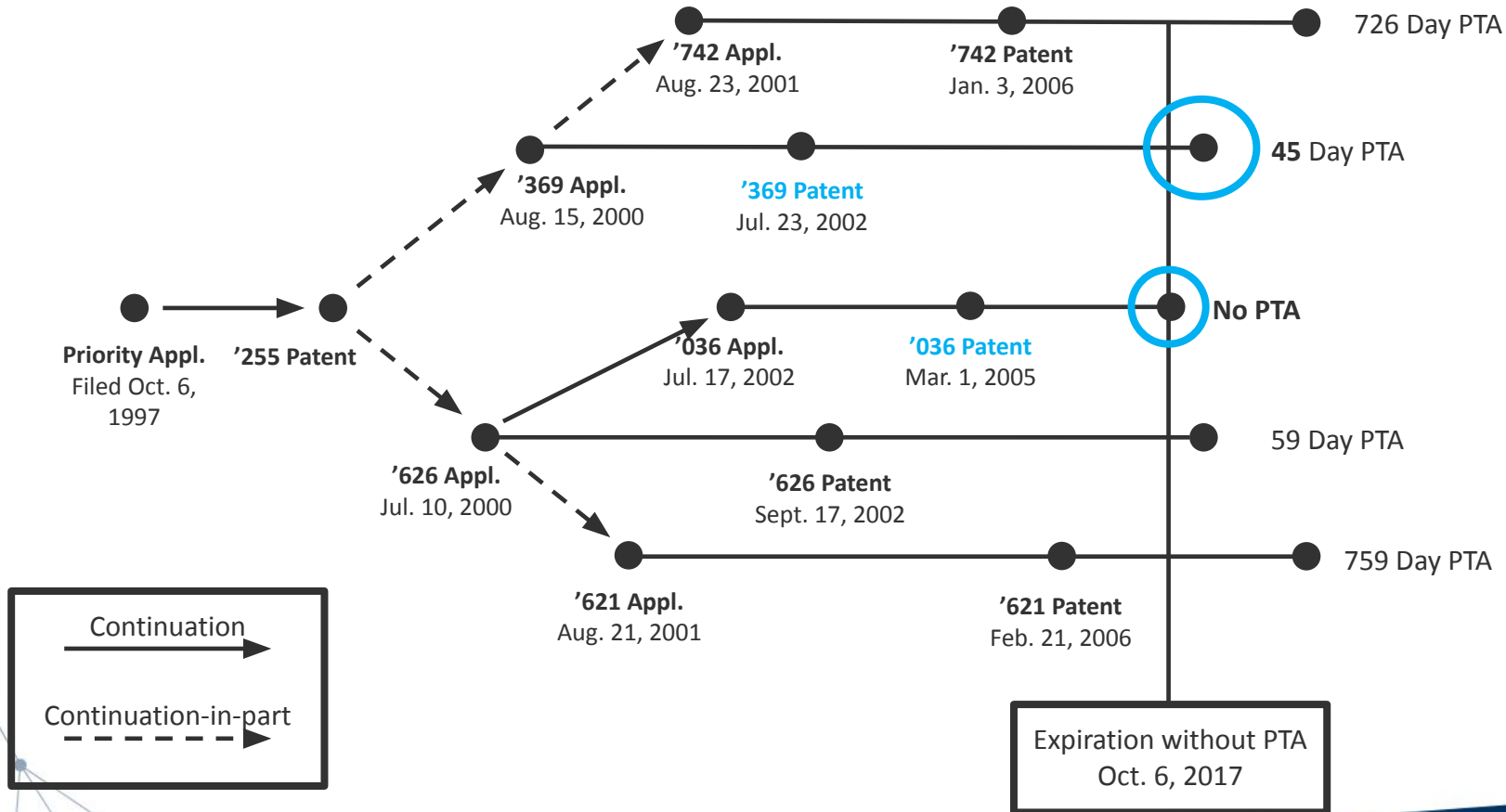


In re Collect: Key Facts



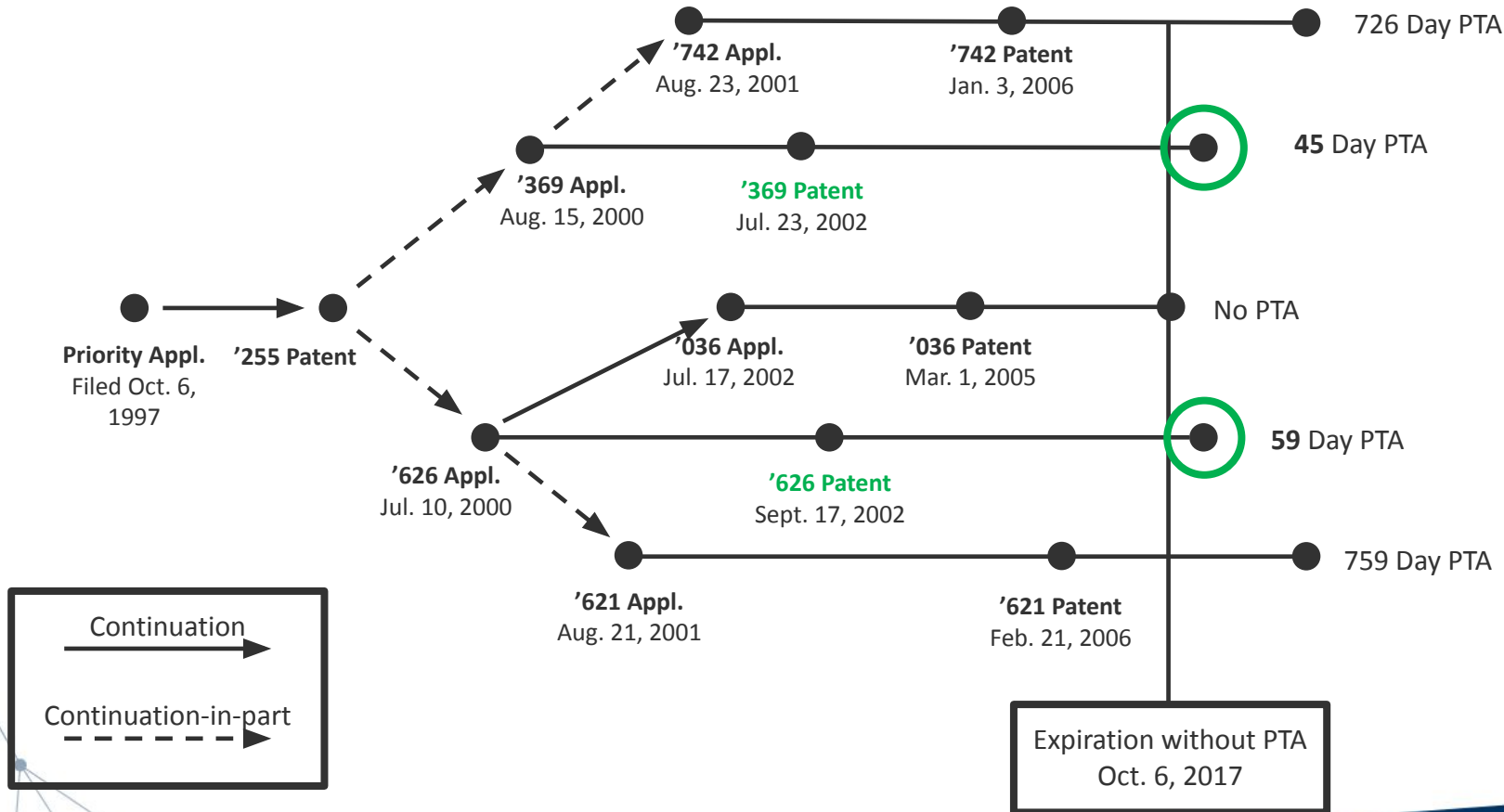
Challenged Patent	Claims	ODP Reference Patent
'742	22, 42 , 58, and 66	'369
'369	1, 17, 19, 21, 22, 27, 49 , 55, and 61	'036
'626	1 , 5, 11, 33, 34, 58, and 64	'369
'621	25, 26, 27, 28, 29, and 33	'626

In re Collect: Key Facts



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In re Collect: § 156 v. § 154 Statutory Language

35 U.S.C. § 156 (PTE)

- § 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....” (emphasis added).

35 U.S.C. § 154 (PTA)

Generally, if issuance of a patent is delayed due to the Patent and Trademark Office...

- § 154(b)(1)(A):

“...the term of the patent **shall** be extended....”

- § 154(b)(1)(B):

“...the term of the patent **shall** be extended....”

- § 154(b)(1)(B):

“...the term of the patent **shall** be extended....” (emphases added).

In re Collect: § 156 v. § 154 Statutory Language

35 U.S.C. § 156 (PTE)

- § 156(c)(3):

“The term of a patent...shall be extended...if the period remaining in the term of a patent after the date of the approval of the approved product...exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years....”

35 U.S.C. § 154 (PTA)

- § 154(b)(2)(B): Disclaimed Term Limitation

“No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.”

In re Collect: § 156 v. § 154 Statutory Language

35 U.S.C. § 156 (PTE)

- § 156(g)(6)(A):
“If the patent involved was issued after the date of enactment of this section, the period of extension determined on the basis of the regulatory review period...may not exceed five years.”
- § 156(g)(6)(B):
“If the patent involved was issued before the date of the enactment of this section...the period of extension determined on the basis of the regulatory review period ...may not exceed five years.”

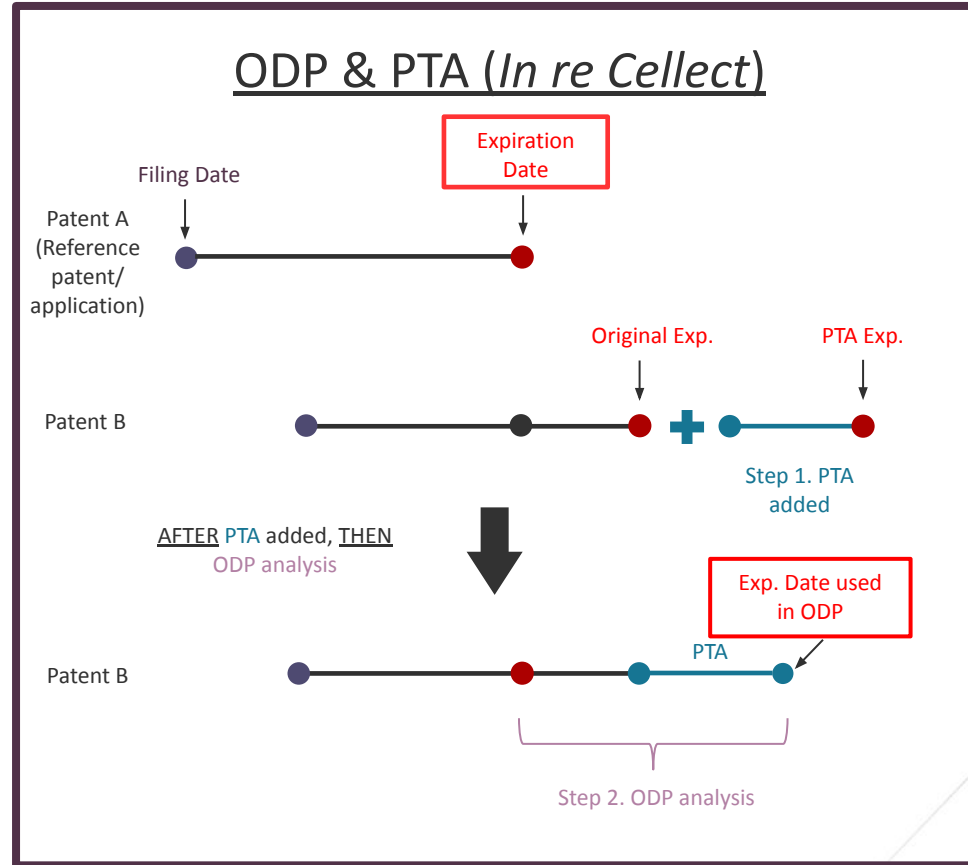
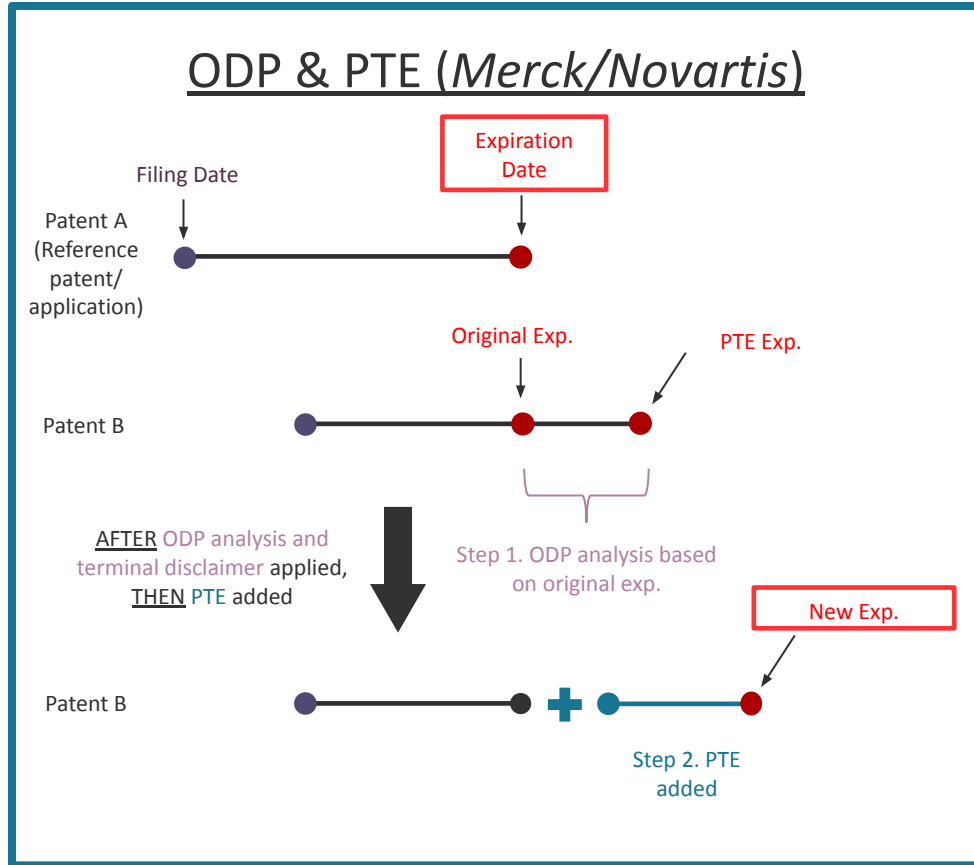
35 U.S.C. § 154 (PTA)

- § 154(b)(2)(B): Disclaimed Term Limitation
“No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.”

In re Collect: Holding

“[W]e agree with the USPTO that **PTA and PTE should be treated differently** from each other when determining whether or not claims are unpatentable under ODP. **PTA and PTE** are dealt with in **different statutes** and deal with **differing circumstances**. We conclude that, while the expiration date used for an ODP analysis where a patent has received PTE is the expiration date before the PTE has been added, the **expiration date used for an ODP analysis where a patent has received PTA is the expiration date after the PTA has been added.**”

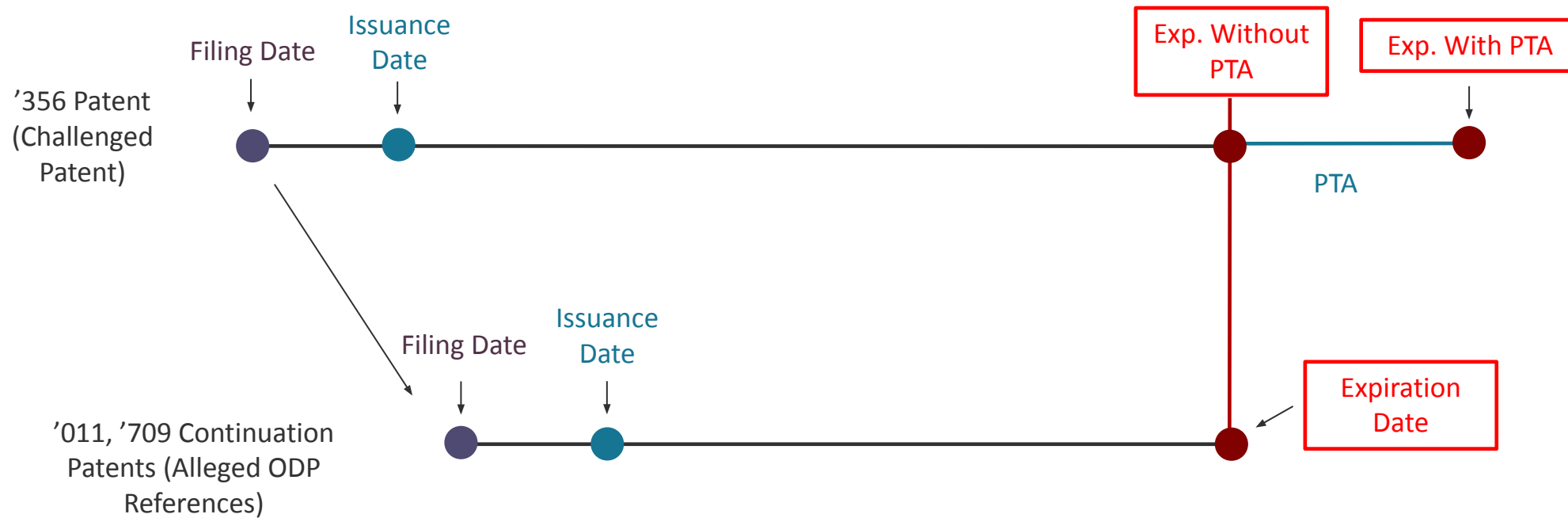
Summary: ODP & PTE/PTA post-*In re Collect*



Post-In re Collect

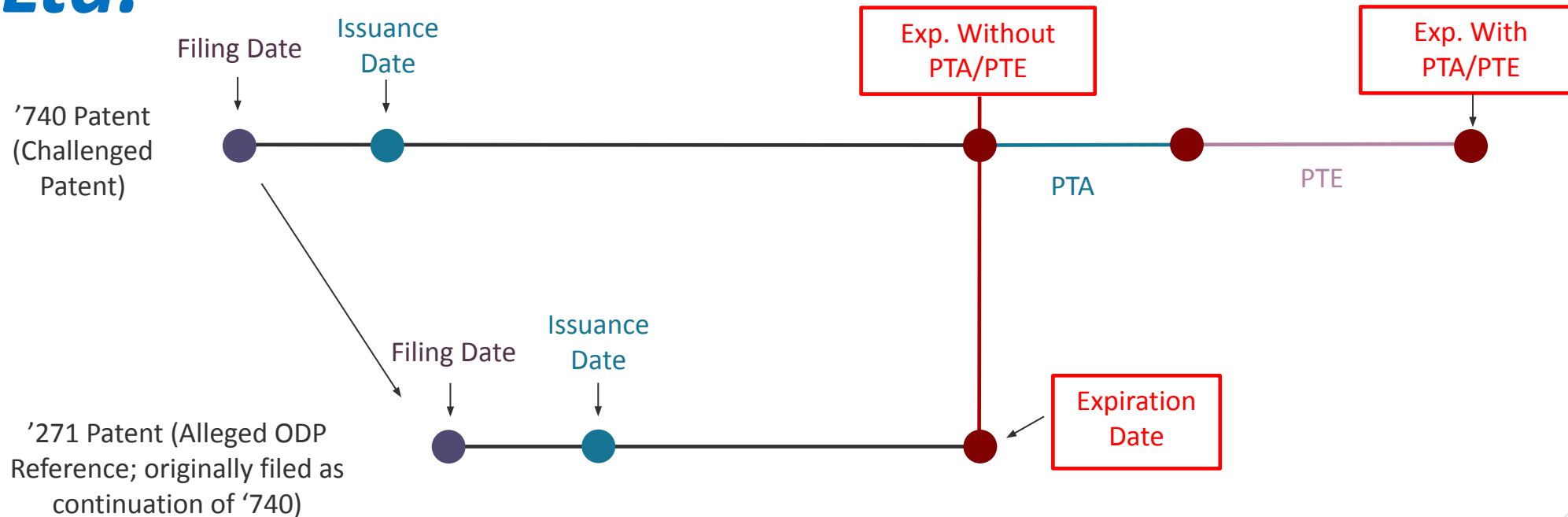
- *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, No. 19-1727, 2023 WL 6295496 (D. Del. Sept. 27, 2023) (Andrews, J.).
- *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, No. 20-985, 2023 WL 8803448 (D. Del. Dec. 13, 2023) (Williams, J.).

Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.



- **'356 Patent invalid over '011, '709 Patents**
- **That '356 Patent was first-filed, first-issued doesn't matter -> look to expiration dates only**

Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.



- ***'271 Patent doesn't qualify as reference against '740 Patent.***
- ***Because '740 Patent claims were filed first, entitled to full term including PTA.***

Reconciling *Allergan* and *Acadia*

Acadia, Note 4:

- “The arguments dispositive in this case do not appear to have been briefed in *Allergan*.”
- “[T]he *Allergan* Court **did not** analyze the language in *Cellect* discussing ‘later-filed obvious variations of earlier-filed, commonly-owned claims.’ Accordingly, the Court does not find itself persuaded by *Allergan*.”

Reconciling *Allergan and Acadia*

- ODP “limits the term of a patent or, at least, ties **later-filed** commonly owned, obvious variations to the expiration date of an earlier-filed reference patent.”

In re Collect, 81 F.4th 1226.

Reconciling *Allergan* and *Acadia*

Acadia, Applying *Cellect*:

- “*If a later-filed patent is used as a reference, the logic and purpose of OTDP is flipped on its head: rather than preventing a patent owner from unjustifiably extending the term of a patent, OTDP would operate to cut off a patent term that would have been valid but for a later-filed patent.*”

Acadia, 2023 WL 8803448, at *7.

Litigation Considerations

- Using ODP as Defendant
- Addressing ODP as Plaintiff

Using ODP as Defendant

- Use an earlier-filed, earlier-expiring patent as ODP reference
 - This includes continuations (**but not** divisional patents, divisionals of divisionals, or continuations of divisionals)
- Can file re-examinations based on ODP challenges (*see In re Collect*)
 - **But note**, IPRs and PGRs cannot review grounds based on ODP; limited to statutory defenses of invalidity
- **Note** that for a challenged patent granted both PTA and PTE, while PTA may be eliminated, PTE can still be added after any disclaimed date

Addressing ODP as Plaintiff

- Identify patents at risk for ODP challenge **early**
- How to respond if there is a risk?
 - Argue safe harbor applies
 - If no safe harbor, argue challenged claims are not obvious
 - File terminal disclaimers (*before* earlier-expiring patent has expired)
 - If patent has PTE & PTA, terminally disclaim PTA -> keep PTE
 - Disclaim only challenged claims under 35 U.S.C. § 253

Addressing ODP as Plaintiff

- What can you **NOT** do?
- Cannot retroactively amend via reissue or reexam to get safe harbor protection

In re Janssen Biotech, Inc., 880 F.3d 1315, 1322 (Fed. Cir. 2018) (“[A] patent owner cannot retroactively bring its challenged patent within the scope of the safe-harbor provision by amendment in a reexamination proceeding.”);

G.D. Searle LLC v. Lupin Pharm., Inc., 790 F.3d 1349, 1355 (Fed. Cir. 2015) (“Simply deleting that new matter from the reissue patent does not retroactively alter the nature of the [] application.”).

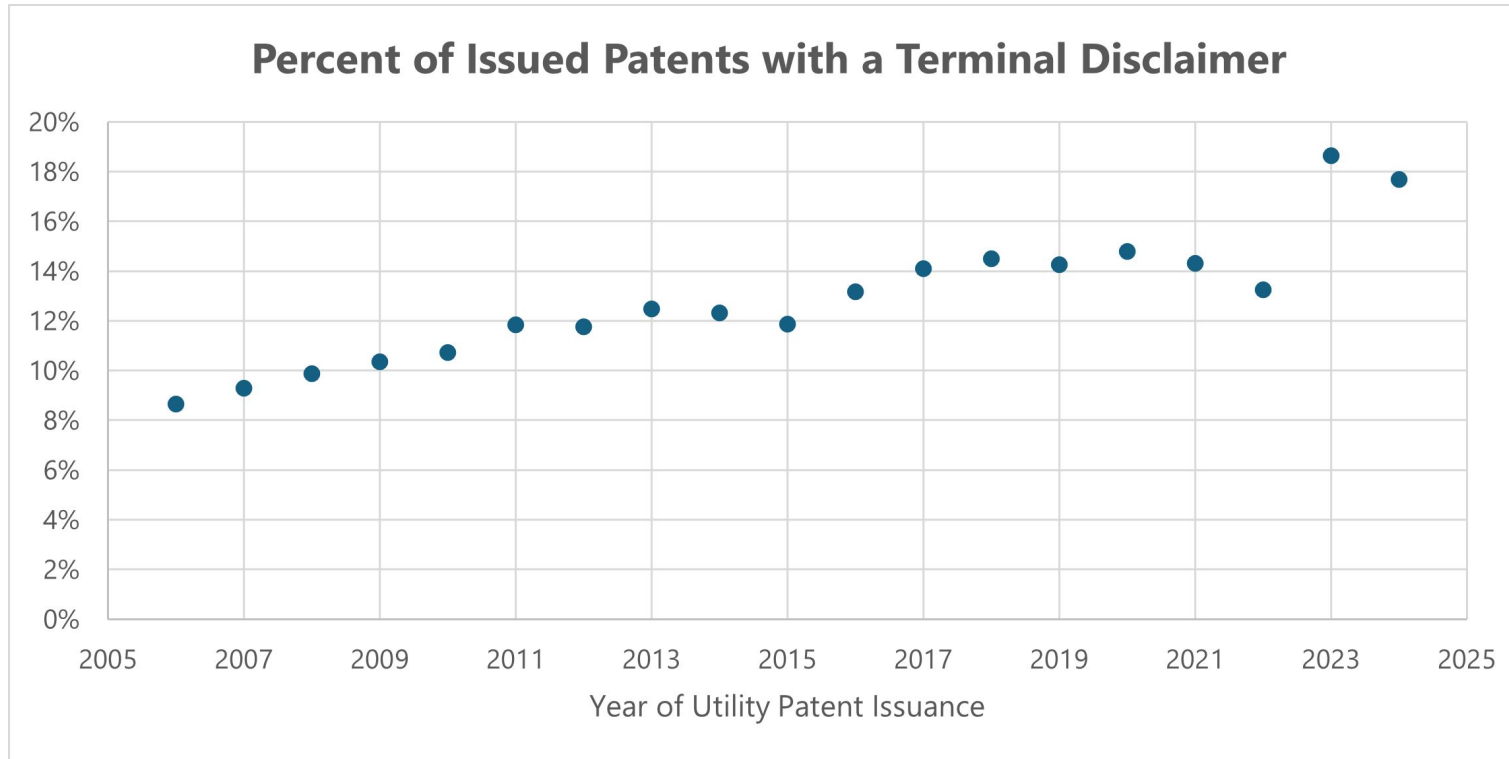
ODP Risks

Invalidity

Patent term

ODP Rejections

ODP is an area of focus for USPTO



[Terminal Disclaimers: A Growing Concern in Patent Practice | Patently-O \(patentlyo.com\)](#) Posted May 10, 2024

Mitigating ODP Risk During Prosecution

- Addressing ODP rejections during prosecution
- Use of § 121 Safe Harbor
- Filing strategy
- Monitoring

ODP Rejections

Most significant prosecution issue when the reference is not prior art

If reference is prior art, must traverse of novelty and obviousness

ODP Rejections

Rejection of patent claims that are not patentably distinct from claims of a reference patent or a co-pending reference application.

A double-patenting rejection is a rejection between either (i) co-pending applications, or (ii) a patent and a pending application.

A double-patenting rejection is based only on the claims of the reference patent/application.

ODP Rejections

A double-patenting rejection is made when the application and the co-pending application or patent either:

Share at least one common inventor;

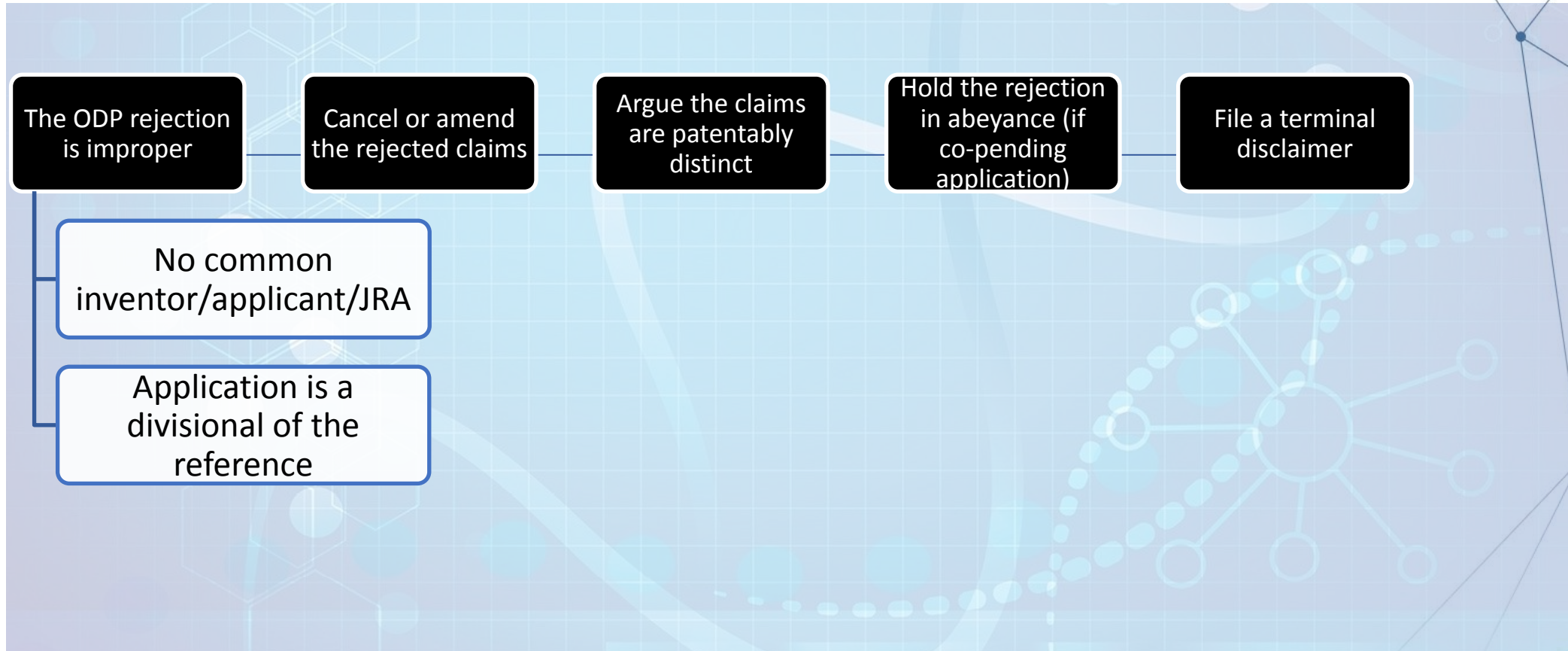
Share at least one common applicant;

Are commonly owned;
and/or;

Are subject to a joint research agreement (JRA).



ODP Response



ODP Response – Argument

Argue the claims are patentably distinct

Similar to obviousness analysis

Specification can (only) be used

Interpret claims
and determine
claim scope

Determine
whether the
results are
unexpected

ODP Response – Terminal Disclaimer

Limits the patent term to the expiration date of the reference patent

Links patents so that they can only be enforced together

Requires common ownership **BUT**

ODP rejections can be made on the basis of a **common inventor**

Safe Harbor

35 U.S.C. § 121 Requirements

1. Restriction requirement

2. Divisional application filed in response to restriction requirement

3. Consonance

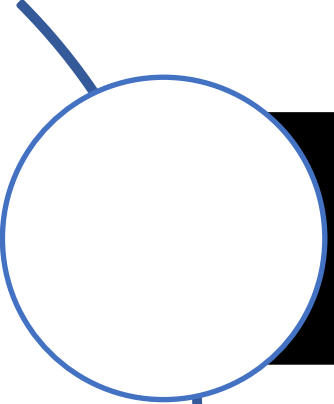


Safe Harbor – Restriction Requirement


Restriction is the practice of requiring an applicant to elect a single, claimed invention for examination when two or more independent inventions and/or two or more distinct inventions are claimed

Typical Restrictions:
(1) Composition vs. methods
(2) Cell vs. protein
(3) Protein vs. nucleic acid

Safe Harbor – Divisional

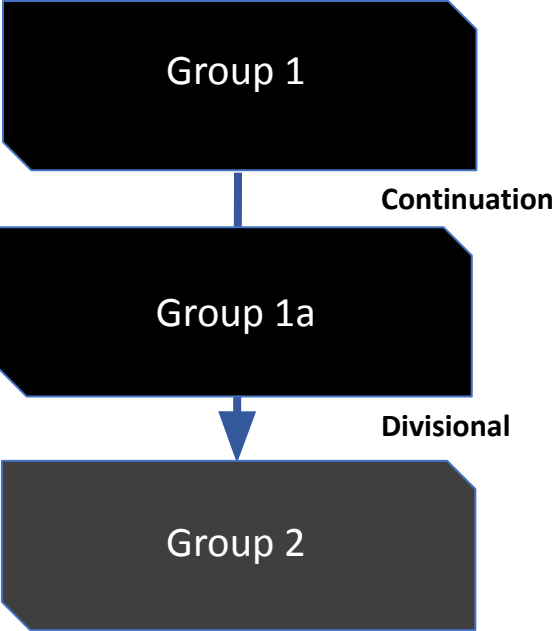
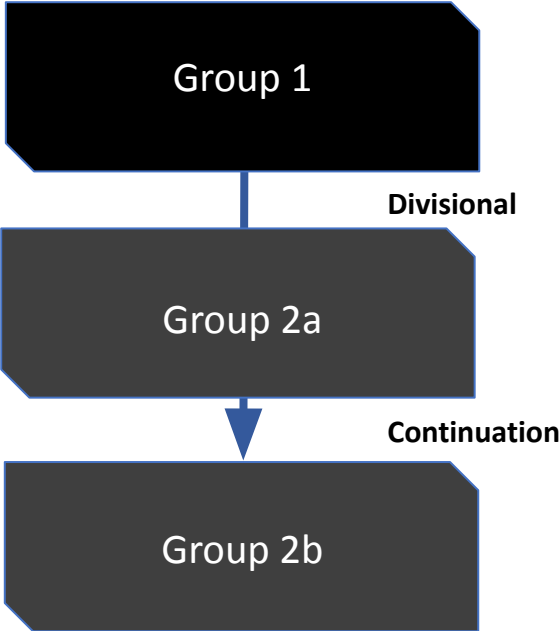
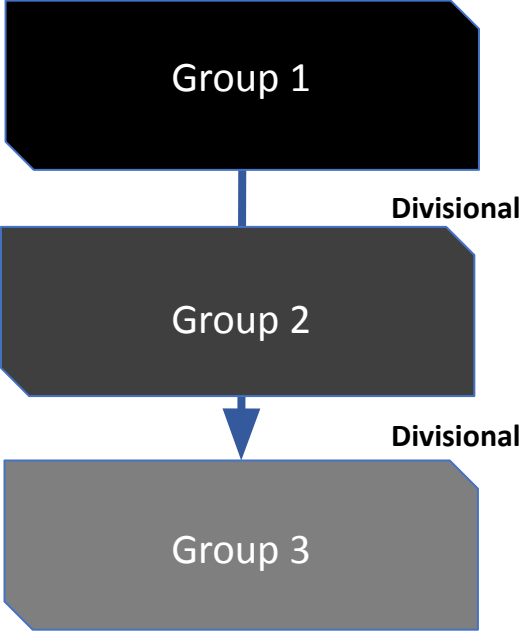


Safe harbor does not apply to continuation applications which could have been filed as a divisional



If a restriction requirement is received in an application and divisionals are filed as a result of the restriction requirement, the safe harbor can protect the descendants of the divisionals even if there are intervening continuations and/or continuations-in-part

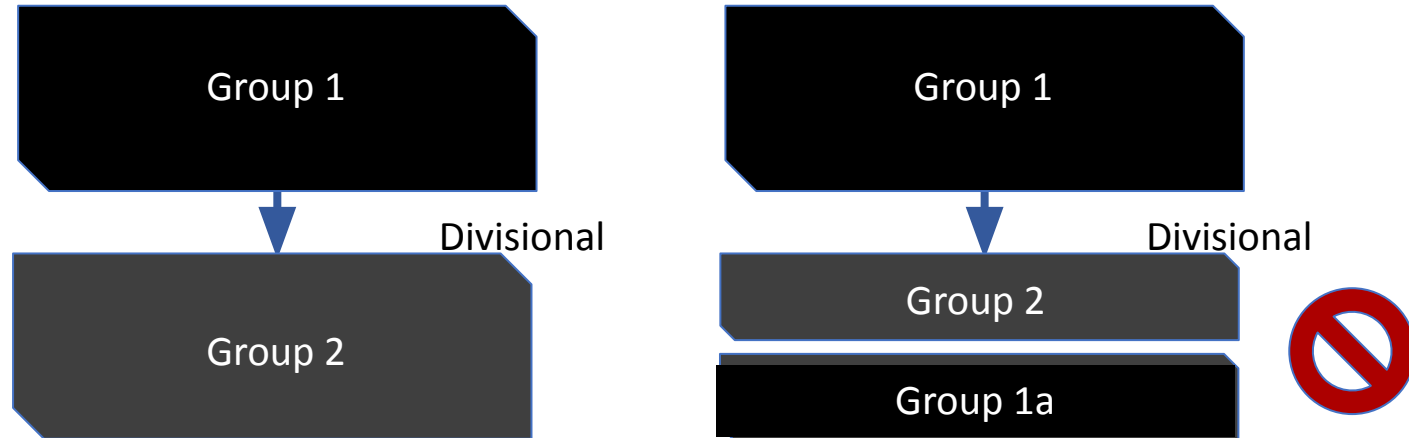
Safe Harbor – Divisional



Safe Harbor - Consonance



Must respect the lines of demarcation set forth in the restriction



Section 121 only applies to restriction requirements that are documented by the US Patent Office in enough clarity and detail to show consonance

Safe Harbor – Restriction Requirement

Consider whether to include related inventions in a single application

Provides safe harbor protection later if restriction is issued

ODP Monitoring

Before paying the issue fee consider ODP implications

- Significant PTA in a family member?
- Later-filed cases which may not be patentably distinct?

Before expiration consider ODP implications

- File preemptive terminal disclaimer?

ODP – Prosecution Tips

- Consider ODP issues from the outset when drafting patent applications
- Trigger restriction requirement by presenting multiple claim types
- File divisional applications (rather than continuations) when possible
- Avoid mixing claim types in divisional applications
- Monitor ODP risk prior to issue fee payment and expiration

Thank you for joining us.

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