

SLW Life Sciences Webinar Series

Obviousness-type Double Patenting (ODP)

From *In re Zickendraht* to *In re Cellect* and Beyond

December 10, 2024

Before We Get Started...



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Panel



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Timeliness of Topic

Evolving case law: *In re Collect* in 2023 followed by *Allergan USA, Inc. v. MSN Laboratories Private Ltd.* just this summer.

Proposed Rulemaking: 89 FR 40439 - Terminal Disclaimer Practice To Obviate Non-statutory Double Patenting

Agreement that patent/application in which the terminal disclaimer (TD) is filed enforceable only if patent is not tied and has never been tied directly or indirectly to a patent by one or more TDs in which: any claim has been finally held unpatentable or invalid by a Federal court in a civil action or by the USPTO.

Extends to patents where a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made.

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IMPACT IF IT HAD BEEN FINAL: holding of lack of enforceability infects entire portfolio.

Agenda

- 1. Explore the origins of the doctrine of ODP**
- 2. Strategies for addressing ODP**
- 3. Review judicial recent developments**



In the beginning: *In re Zickendraht*, 319 F.2d 225 (C.C.P.A. 1963)

Examiner Rejection: instant claims not patentably distinguishable from claims of patented prior art from the same inventor.

Judicial Opinion: instant claims should have been rejected for double patenting but disagreed with the basis for the court's conclusion.

The rule was summarized as follows: “**claims to inventions closely related to the invention claimed in a patent and not patentably distinguishable therefrom must be included in the same patent unless the applicant has been forced to make them in a separate application by a requirement of restriction.**”

Judge Rich advised applicant to file a terminal disclaimer to avoid a double patenting rejection.

In re Zickendraht progeny

Courts have extended this prohibition “to preclude a second patent on an invention which ‘would have been obvious from the subject matter of the claims in the first patent, in light of the prior art.’” *In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985).

Thus, **obviousness-type double patenting (ODP)** (also known as “non-statutory double patenting”) is a judicially created doctrine intended to prevent an improper time-wise extension of a patent right by prohibiting the issuance to a single inventor of claims in a second patent which are not “patentably distinct” from the claims of a first patent. *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997).

When can ODP arise?

During prosecution. Of course.

ODP is an affirmative defense during litigation as it is a ground for invalidating one or more claims of a patent. *See, e.g., Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991); *Geneva Pharms. Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003).

Invalidation Rates for ODP

Don't have statistics on invalidation rate for ODP.

But . . .

IP Watchdog (PTAB invalidation rates):

“[S]ince 2021, the invalidation rate has been increasing and is currently at 71% for the first two quarters of 2024. In 2023, all challenged claims were found invalid 68% of the time. These are daunting statistics for patent holders.”

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Why is ODP so odd?

Filing dates do matter. However, a later-filed application or patent can be used as the basis of ODP for an earlier-filed application or patent.

This can include patents from different assignees!

If the first (earlier) patent has expired, a terminal disclaimer (TD) cannot be filed and the second (later) patent will be invalid for ODP.



Standard for ODP

Claims of a second patent or application are not distinct (anticipated or obvious) in view of the claims of the first patent or application.

One-way test (default): is the claim at issue patentably distinct over the reference claim?

Two-way test (rare): Applies only in cases where the applicant could not have filed the claims in a single application **and** there is administrative (U.S. Patent and Trademark Office) delay.

Two-way test (briefly)

- “The two-way exception can only apply when the applicant could not avoid separate filings, and even then, only if the PTO controlled the rates of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application” *In re Berg*, 140 F.3d 1428 (Fed. Cir. 1998).
- “[P]rosecution choices resulted in the foreseeable consequence that the ’685 patent issued before the application claims on appeal. Given these circumstances, and because it is undisputed that the PTO was not solely responsible for the delay, Hubbell is not entitled to a two-way obviousness analysis.” *In re Hubbell*, 709 F.3d 1140, 1150 (Fed. Cir. 2013).
- In a situation where delayed issuance equated to later expiration, applicant’s voluntary decision to obtain early issuance of claims directed to a species and to pursue prosecution of previously rejected genus claims in a continuation is a considered election to postpone by the applicant and not administrative delay. *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993).

Two-way test (briefly)

- Necessary to apply the obviousness analysis twice, first analyzing the obviousness of the application claims in view of the patent claims, and then analyzing the obviousness of the patent claims in view of the application claims.
- Non-statutory double patenting rejection based on obviousness is appropriate only where **each analysis** leads to a conclusion that the claimed invention is an obvious variation of the invention claimed in the other application/patent.
- **If either analysis does not lead to a conclusion of obviousness**, no double patenting rejection of the obviousness-type is made.
- ONE **BENEFIT** OF TWO-WAY TEST: reduces risk of invalid ODP rejections when claims are merely related but not actually obvious variants.

Standard for ODP

Obviousness analysis under ODP is analogous to an obviousness analysis under 35 U.S.C. § 103, except that:

The first patent or application is not considered prior art.

Reference to the specification of the first patent or application may be appropriate, *e.g.*, for claim construction.

Avoiding ODP

Preempt ODP

- Maintain “consonance” such that there is safe harbor under 35 U.S.C. § 121 (section relating to divisional applications).
- Consider canceling claims to other groups of inventions in response to restriction requirement. If examiner rejoins, safe harbor is forfeit.
- Consider whether **election-of-species requirements** can create safe harbor between claims in one patent over those on a related patent in which such a requirement is imposed. *St. Jude Med., Inc. v. Access Closure, Inc.*, 729 F.3d 1369 (2013).

Overcoming ODP

Argue that claims are patentably distinct:

- for compound claims **cannot rely on lead compound analysis.**
- evidence of secondary considerations should be considered, when offered, in an ODP analysis.
- remove overlap between pending claims and reference claims.

Overcoming ODP

“If a provisional non-statutory double patenting rejection is the **only rejection remaining in an application having the earlier patent term filing date**, the examiner should withdraw the rejection in the application having the earlier patent term filing date and permit that application to issue as a patent, thereby converting the provisional non-statutory double patenting rejection **in the other application into a non-statutory double patenting rejection upon issuance of the patent.**” MPEP § 804.



Overcoming ODP

File a terminal disclaimer and agree that:

- the patent issuing from an application will have **an expiration date of the reference patent/application.**
- any patent issuing from an application and the reference patent/application, will have **common ownership during their common patent term.**
- any patent issuing from application and reference patent/application only **enforceable during the common patent term so long as the two patents are commonly owned.**

But . . .

What if the application in question and reference patent are held by different assignees?

Patents linked by a TD **will only be enforced while commonly owned.**

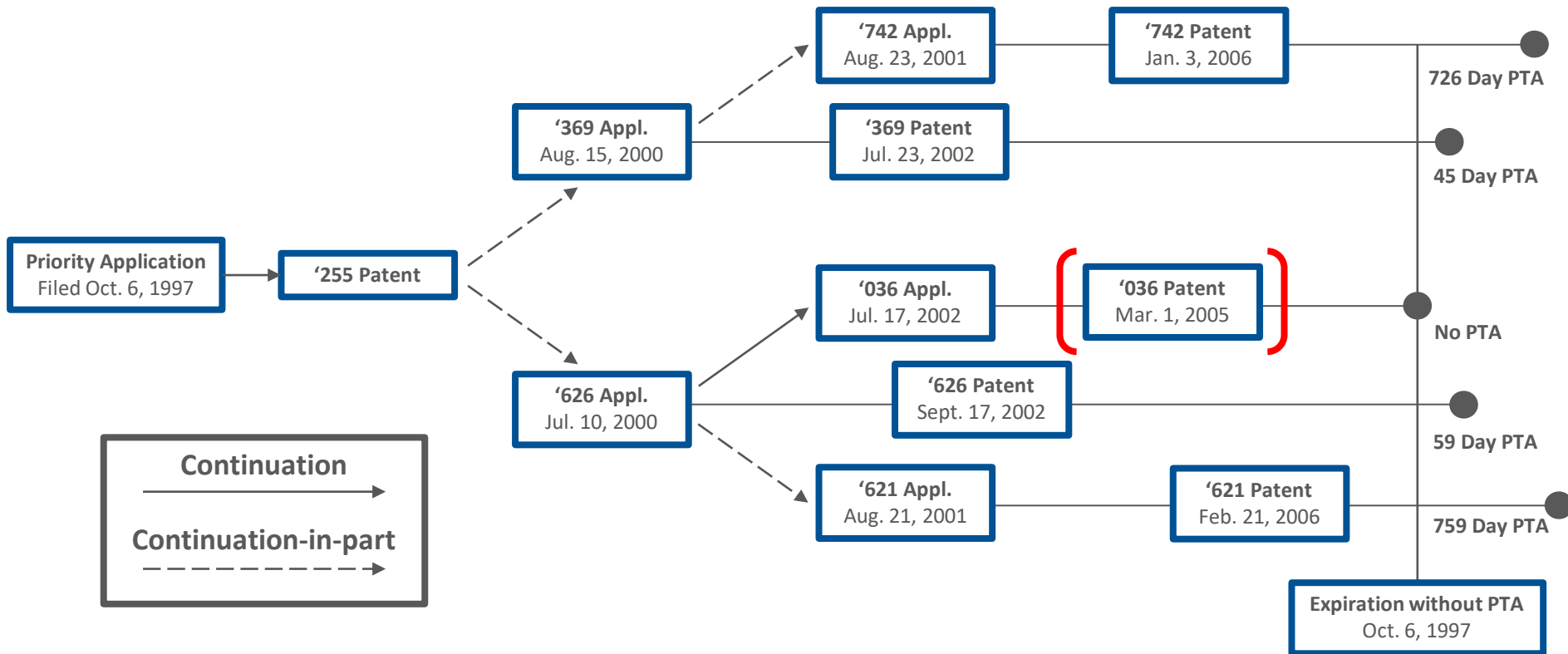
TD can reduce the patent term by limiting Patent Term Adjustment (PTA) (the term cannot extend beyond that of the earlier patent). 35 U.S.C. §§ 154(b)(2) and 253.

Judicial Developments

- *In re Collect*, 81 F.4th 1216 (Fed. Cir. 2023) – expands ODP.
- *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, No. 24-1061 (Fed. Cir. 2024) – interprets *In re Collect*.



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



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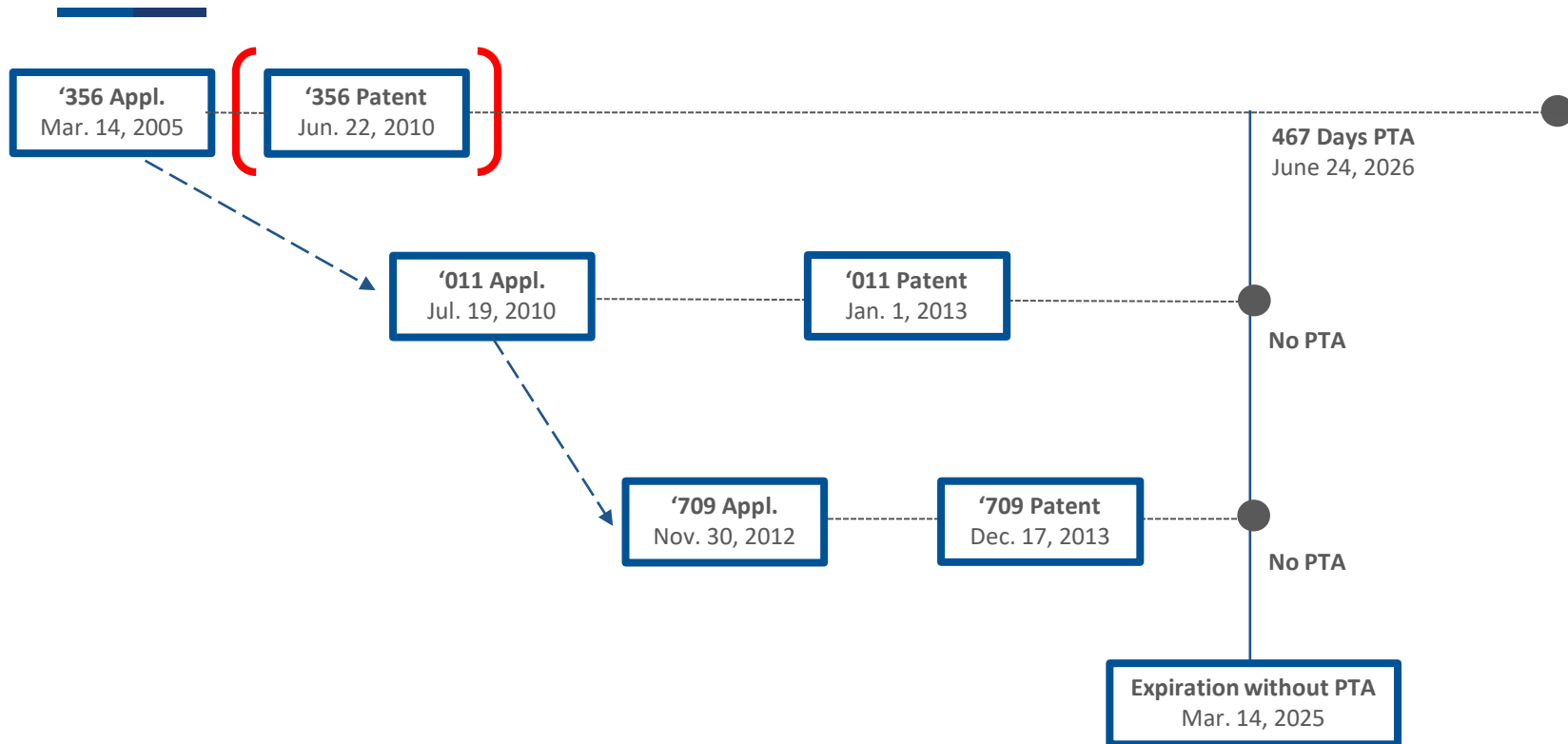
A later-expiring patent can be held invalid for obviousness-type double patenting (ODP) in view of an earlier-expiring, commonly owned patent, *even if the later expiration date is solely due to patent term adjustment (PTA)*.

Patent Term Extension (PTE) was held to be separate and not considered for ODP.

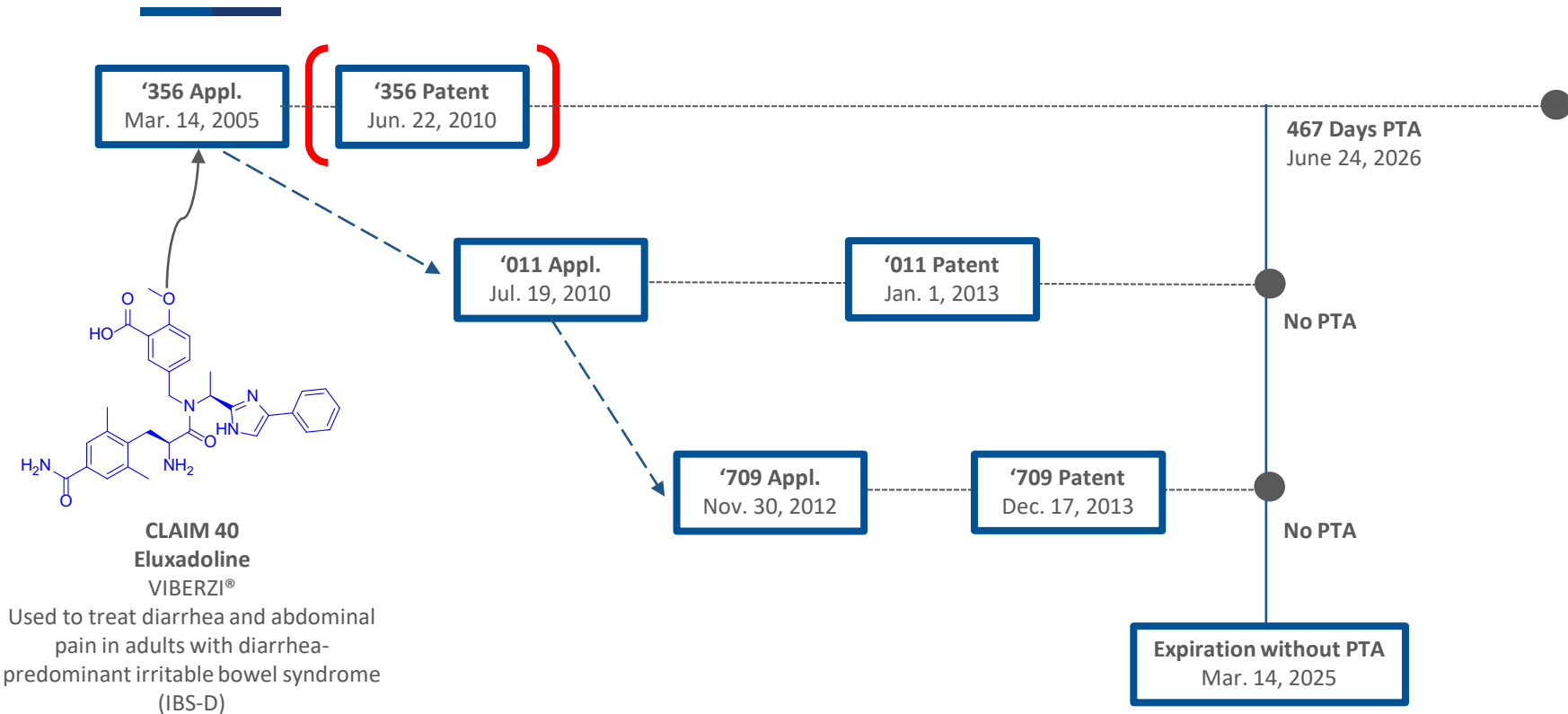
This expands the scope of potentially invalidating prior art.

U.S. Supreme Court denied petition for *certiorari* in October 2024.

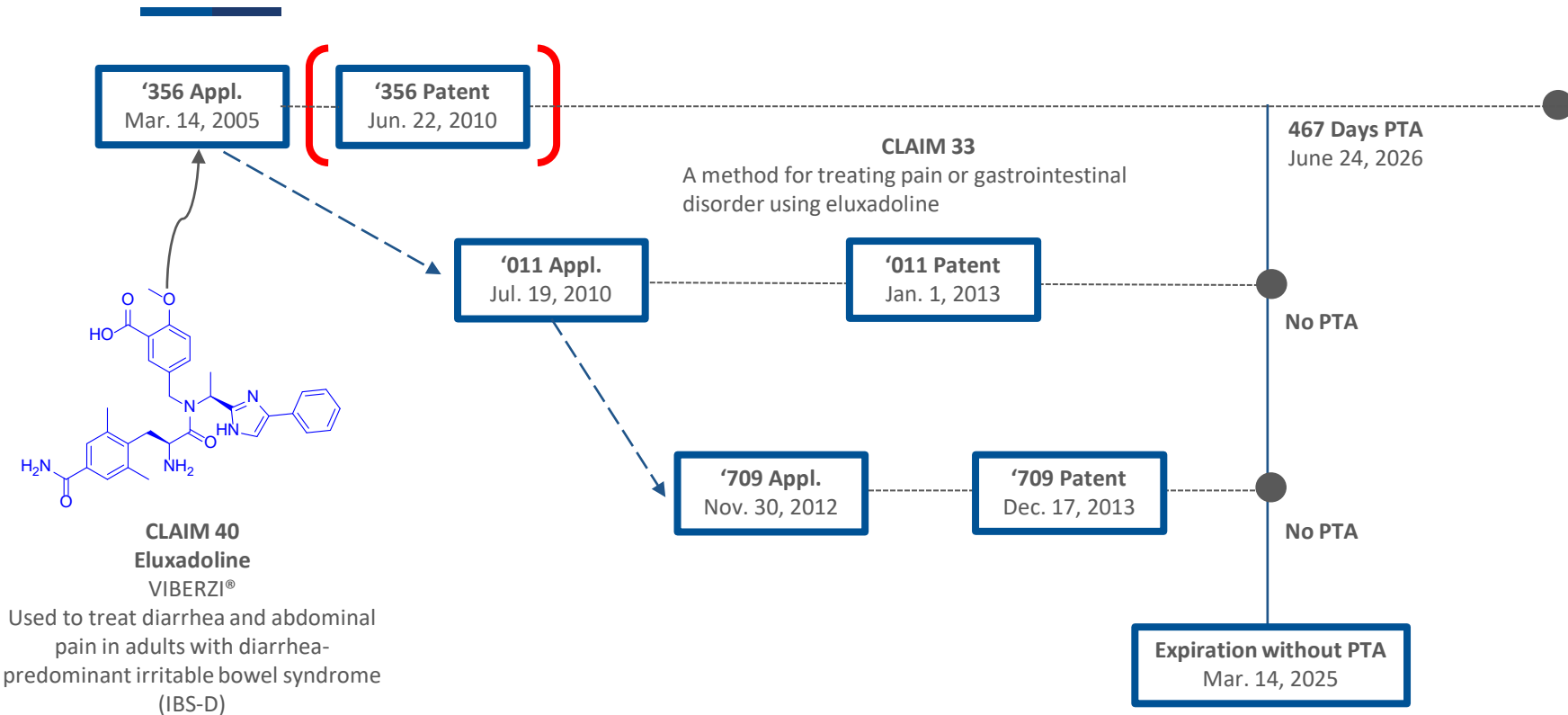
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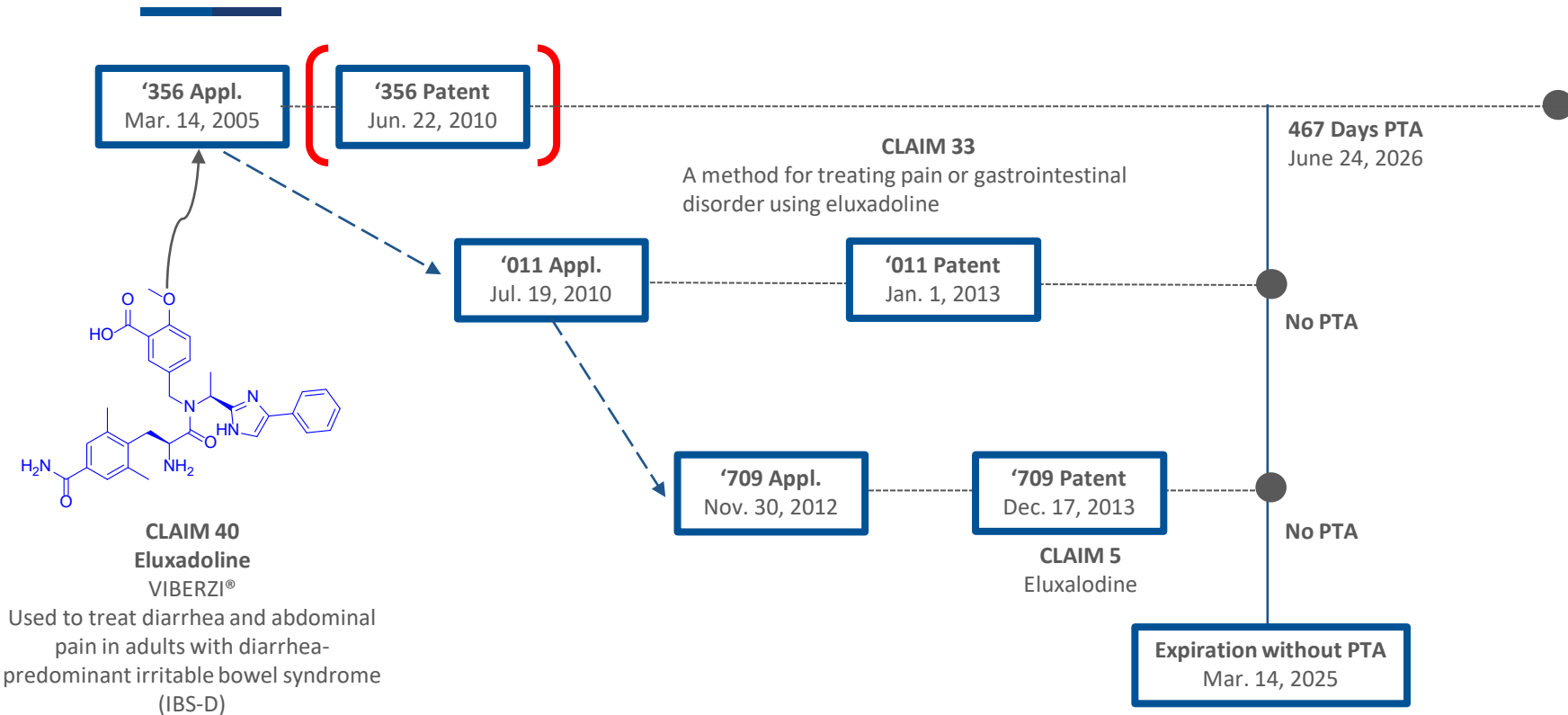
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This decision limits the application of obviousness-type double patenting.

Judicial Decision: **a first-filed, first-issued, later-expiring patent claim** cannot be invalidated for obviousness-type double patenting by a later-filed, later-issued, earlier-expiring reference patent claim having a common priority date.

“[T]he fact that the ’356 patent expires later is of no consequence here because it is not a “second, later expiring patent for the same invention.”

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Questions?