



# Advanced Topics in Double Patenting



**A Webinar for  
Patent Prosecutors and Litigators**

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- Obviousness-type Double Patenting (“OTDP”)
- Current USPTO practice
- Recent Federal Circuit and Board decisions
- Lessons and analysis
- A real-life conundrum

- Obviousness-type double patenting ("OTDP") is an equitable doctrine with two main goals:
  - Avoiding unjust extension of patent term
    - If a patentee seeks to obtain multiple patents on essentially the same invention, they should expire at the same time
  - Avoiding multiple lawsuits by different parties on patents arising out of the same inventive activities
    - Duplicative lawsuits unfairly penalize potential infringers and complicate the path to market for the patented technology

# Terminal Disclaimers

- OTDP can be resolved with a terminal disclaimer ("TD") that has two key provisions:
  - Any term of a patent that outlasts a reference patent is disclaimed; and
  - Both patents must be commonly owned or enforced
- Although the name "terminal disclaimer" suggests only the first of these requirements, the second provision is an inextricable part of a TD
- In prosecution, this typically means disclaiming the term of a pending application relative to an issued patent or another pending application

- The law of OTDP evolved while U.S. patents lasted 17 years from their issue date
  - Each successive patent would necessarily expire later and later, so an application would always outlast an issued patent, regardless of filing order
  - A standard TD always addressed the underlying equitable issues
- Patents granted on applications filed since June 8, 1995 expire 20 years from their earliest claimed PCT or U.S. non-provisional priority filing date, regardless of when they issue
  - A pending application could expire before a previously issued patent
  - A standard TD doesn't really address this situation, nor do the established procedures for assessing double patenting

## Considering an application and a patent:

- One-way obviousness:
  - Applies if the application at issue is the later-filed application or both are filed on the same day
  - Looks only at the obviousness of the application's claims over those of the patent
- Two-way obviousness:
  - Applies if the application has the earlier filing date, the applicant could not have filed the patented claims in the earlier-filed application, and administrative delay is solely responsible for the earlier-filed application not issuing first
  - Requires finding the application claims obvious over the patent claims *and vice versa*

- MPEP § 1490 – not often referred to by examiners – addresses terminal disclaimers and double patenting as well
- It clarifies the meaning of “earlier-filed” to take into account priority claims under 35 U.S.C. § 120
  - It also states that if two pending applications are entitled to the same priority date, terminal disclaimers are required in **both**, perhaps on the premise that it’s impossible at that point to know which will expire later
- So the story at the USPTO is a bit unclear and illogical
- How about the courts?

## Recent Cases: In re Fallaux (F.C. 2009)

Fallaux and Vogels had two families of post-GATT applications with a common inventor – but with different assignees

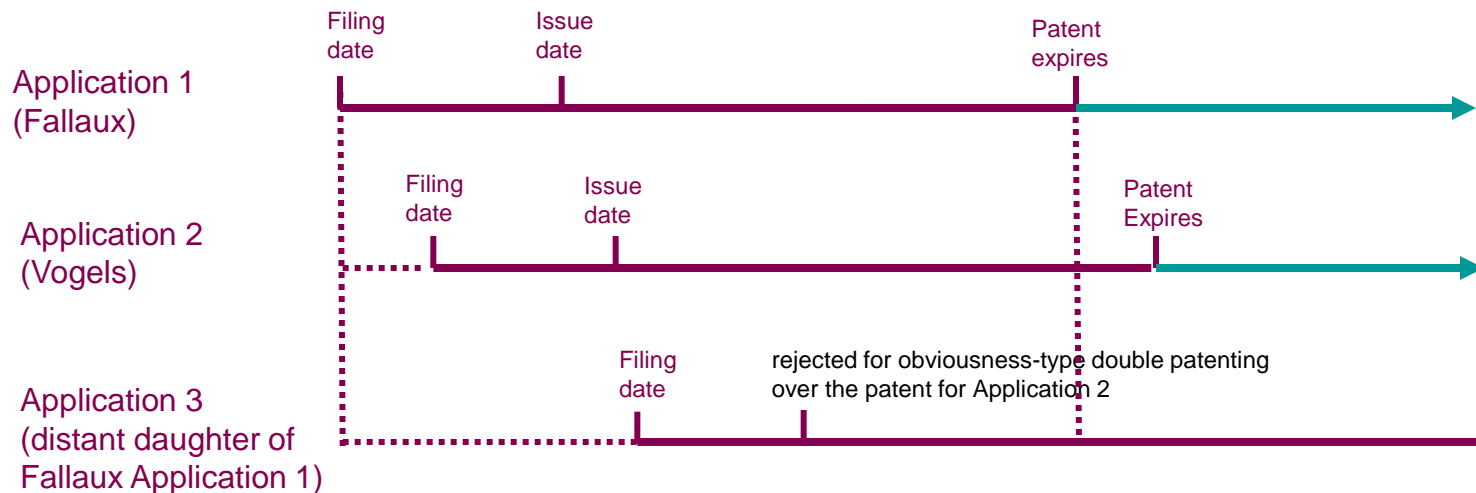
Fallaux – Filed	Issued	Vogels – Filed	Issued
1995	1999	1998	2002
	2001		2002
	2003		
	2006		
2003	<i>at issue</i>		

Fallaux’s 2003 claims are anticipated by Vogels’ issued claims

**Is this a double patenting issue?**



# Recent Cases: *Fallaux* (Fed. Cir. 2009)



- Applications 1 and 2 do not have common ownership
- Were commonly owned to begin with, then sold separately
- Application 3 is a proper daughter of application 1
- Application 3 is rejected for OTDP over the patent issued from application 2

- Even if the second invention is patentable over the first, the USPTO attributes pendency of Application 3 to applicant delay, so a one-way analysis is applied
- A standard terminal disclaimer **cannot** be filed without common ownership or at least a joint research agreement (JRA)
- The only option recognized by the USPTO rules is to amend the claims to avoid the problem
  - There may not be support in the earlier-filed application for an amendment that preserves meaningful claim scope

## Recent Cases: *Fallaux* (Fed. Cir. 2009)

- Fallaux said it should have been a two-way test
  - Was the filing of serial continuations due to administrative delay by the USPTO?
  - Could the 2003 claims have been filed in one of the earlier applications?
  - Was Fallaux just engaging in typical prosecution with no ulterior motive?
  - In fact, the Fallaux patent would expire before all Vogels patents; no “unjust” term extension possible

# Creative Solution?

- No issue of unjust timewise extension – no actual disclaimer is needed
  - Even if patent term adjustment created an issue, any excess term could be disclaimed using an ordinary disclaimer
- Primary equitable issue is multiple independent lawsuits
- The two assignees could simply agree that the patents to the first and second inventions will be commonly enforced
  - This agreement would eliminate the threat of multiple parties suing an infringer on related patents no less effectively than the corresponding provision of a standard TD
  - This is the same principle behind the JRA terminal disclaimer; no apparent reason for equity to require an actual JRA
  - Thinking ahead: a provision of this type might be inserted into a license agreement in case the relationship sours later on

## Recent Cases: *Fallaux* (Fed. Cir. 2009)

- Federal Circuit sided with Board: Fallaux bears at least some (if not all) responsibility for late filing of pending claims, so one-way test is appropriate
- Unjust extension of term still possible for post-GATT cases, due to patent term adjustment or patent term extension
- Even if there were no unjust extension of term, common ownership issue alone would bar allowance of Fallaux application
- In a footnote, Federal Circuit declined to rule on propriety of triggering double patenting on a common inventor

## Recent Cases: *Fallaux* (Fed. Cir. 2009)

- A patent term extension is added to the disclaimed term of a patent with a terminal disclaimer
- Why would the Federal Circuit imply that patent term extension could result in an unjust extension of patent term?
  - What about patent term adjustment?
  - Doesn't this amount represent the delay attributable solely to administrative delay in the USPTO?
- Fallaux tried to file terminal disclaimers, but original assignee had sold Fallaux patents and Vogels patents to different parties (not commonly owned, no joint research agreement)
  - Why shouldn't Fallaux be able to disclaim separate enforcement?
- Bad facts make bad law?

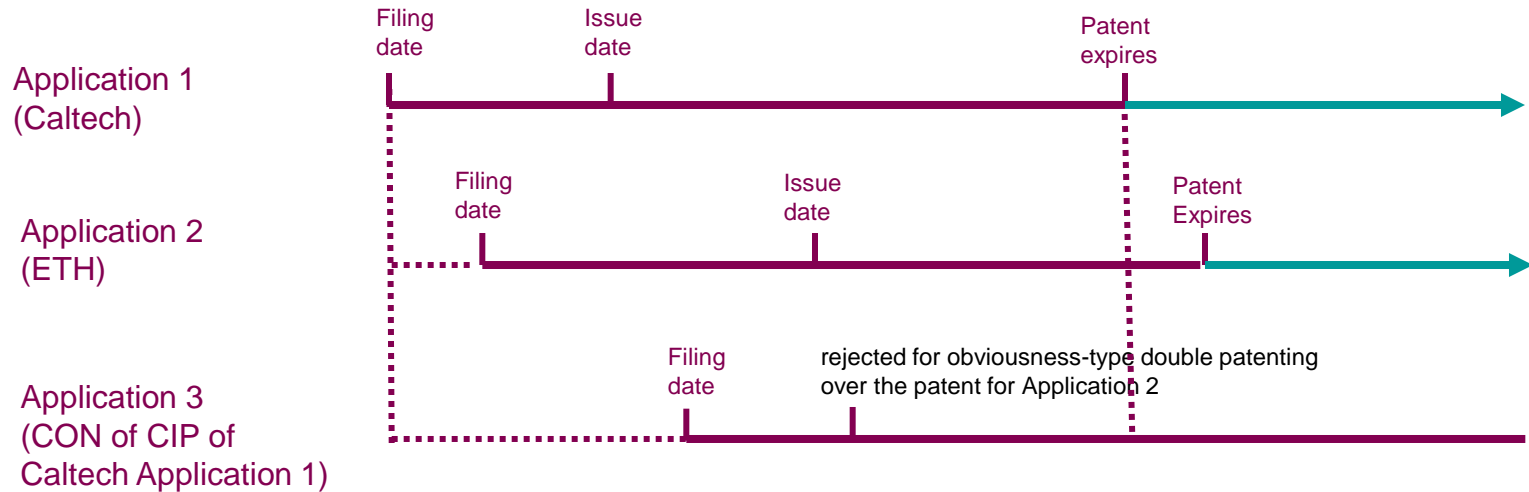
## Recent Cases: *In re Hubbell* (F.C. 2013)

Caltech professor moves to ETH and continues related research

Caltech – Filed	Issued	ETH – Filed	Issued
1998	2001	2002	2009
2001 (CIP)	(abandoned)		
2003	<i>at issue</i>		

Caltech’s 2003 claims are anticipated by ETH’s issued claims. Is this any different from Fallaux?

# Recent Cases: *Hubbell* (Fed. Cir. 2013)



- Applications 1 and 2 do not have common ownership
- No JRA between Caltech and ETH
- Application 3 is a proper daughter of application 1
- Application 3 is rejected for OTDP over the patent issued from application 2
- USPTO analysis as in Fallaux



## Recent Cases: *Hubbell* (Fed. Cir. 2013)

- Short answer: No
- Majority opinion rejected application of two-way test here, and rejected terminal disclaimers as equitable remedy here
  - Said that such a terminal disclaimer would not be authorized by the rules
  - But isn't that an awfully narrow reading of the rules, and isn't the statute broad enough to cover this situation anyway?
  - And wasn't the whole idea of double patenting and terminal disclaimers outside the statute to begin with?
  - Couldn't the court allow an equitable way out for Caltech?
    - Dissent (Newman) would have allowed terminal disclaimer: "If there indeed is obviousness-type double patenting, then a terminal disclaimer is necessarily available"

## Recent Cases: *Hubbell* (Fed. Cir. 2013)

- Should ETH have entered into a joint research agreement with Caltech when Hubbell came on board?
- What does this mean for companies that hire scientists for their technical expertise?
- What about companies that license university technology and then continue development in house?
- Who are we “protecting”?
- Does the one-way/two-way test rubric really make sense in a post-GATT world?
  - Applicants can’t do much to actively extend their patent term; that’s in the hands of the PTO

# Recent Cases:

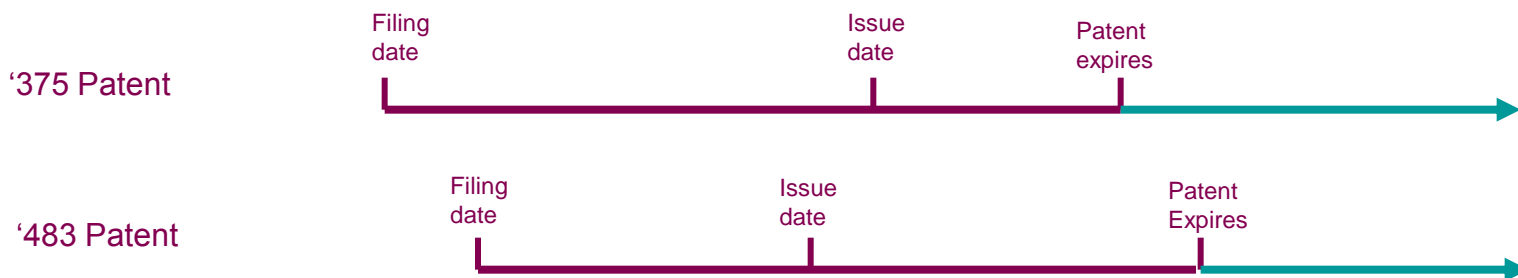
## *Gilead v. Natco* (F.C. 2014)

Gilead has two closely-related patents:

	<b>5,952,375</b>	<b>5,763,483</b>
Priority	2/27/95	
Filed	2/26/96	12/27/96
Issued	9/14/99	6/9/98
Expires	2/27/15	12/27/16

- Gilead filed a terminal disclaimer in the '375 patent before it issued
- Natco and Gilead disagreed whether the '375 patent could serve as an OTDP reference against the earlier-issued '483 patent
- The district court sided with Gilead, but the Federal Circuit sided with Natco

# *Gilead v. Natco* (Fed. Cir. 2014)



- Simple: two post-GATT cases, the first filed is the second to issue
- Can the issuance of the '375 patent impact the established patent term of the '483 patent?

## *Gilead v. Natco* (Fed. Cir. 2014)

- Federal Circuit states the principle that, after a patent expires, the public should be free to use the claimed invention and ***all obvious variants of it!***
- Federal Circuit explicitly excepted patents to patentably distinct inventions (footnote 5)
  - But isn't this way of casting the problem a complicated oversimplification?
  - What was the matter with “unjust timewise extension”?
  - Gilead's earlier-expiring patent has a claim covering three structures with three unspecified stereocenters (up to 8 stereoisomers for each compound), the later-expiring patent a single stereoisomer of one compound – obvious?
  - Even if it is, would Gilead's situation be “unjust”?

## *Gilead v. Natco* (Fed. Cir. 2014)

- Rader dissented, saying that the patent term concerns are essentially eliminated in a post-GATT world
  - Isn't this type of situation one where it actually would make sense to cut off the patent term?
  - Rader posits, though, that Gilead “paid” for the extension by giving up earlier priority dates
- But he endorsed the filing of a terminal disclaimer in the first-expiring patent to enforce co-ownership of the two patents
- He also disagreed with equating expiration with FTO, as well as finding double patenting based only on a common inventor (and not a common assignee)

## Recent Cases: *AbbVie* (Fed. Cir. 2014)

- AbbVie licensed a patent from the Kennedy Institute of Rheumatology
- A second patent, a granddaughter continuation of the licensed patent, was not covered by the license
- The second patent's priority claim did not include the first patent's priority documents, so it gained about four years of patent term plus about two years of PTA
- While this is a classic scenario for double patenting, the court took pains to cite *Gilead* and adopt its holding and analytical approach

## Is It Really This Illogical?

- *Ex parte Martek* (BPAI 2013)
- Martek filed a series of pre-GATT applications starting in 1988, including one 6/7/95 that issued 12/16/97 (exp., with TD, 11/2014)
- Martek filed a CIP in 1992, and a continuation of the CIP on 3/15/99 (exp. 2008), which ultimately issued as a patent
- The earlier patent entered reexamination and was rejected over the later patent for double patenting



## *Ex parte Martek (2013)*

- The Board reasoned:
  - The claims of the CIP patent couldn't have been filed in the first 1988 application, but could have been filed in 1992. Therefore, it's at least partly the applicant's fault that the second patent issued after the first, so the one-way test applies.
- Result: Actual filing of an “improvement” application after filing and issuance of a “base” application served to remove some of the natural patent term of the “base” patent
- Martek offered to file a “disclaimer” that, without ceding patent term, would require co-ownership of the two patents
  - The board scoffed at this as consistent with a double-patenting problem in fact (Huh?)

## *Ex parte Martek (2013)*

- Note that at the time of the decision, the second patent had expired – but the Board noted that it was still enforceable against those who infringed shortly before it expired, so the threat of suit from multiple parties was still real
  - Some case law prohibits filing a terminal disclaimer after expiration of one of the involved patents
  - Would that have blocked Martek from filing the type of disclaimer they sought to file?
- These days, examiners would extract a terminal disclaimer in the second patent (the first to expire) before allowing it to issue – if the claims indeed were obvious over the claims of the first patent

## Is It Really This Illogical? (Part 2)

- *Ex parte Pfizer* (BPAI 2010)

#		Filed	Issued
1	PCT	5/13/94	10/22/02
2 (270)	PCT	10/16/95	8/8/00
3 (945)	DIV of 2	4/3/00	3/18/03
4 (511)	PCT	10/16/95	12/2/03

- 2, 3, and 4 all claim treatment of erectile dysfunction with structurally defined PDE inhibitors, and state a preference for oral administration
- 1 claims oral administration of any selective PDE inhibitor
- Prior art shows oral administration of other PDE inhibitors
- 1 gets reexamined

## *Ex parte Pfizer (2010)*

- The examiner insisted 1 faced double patenting over 2, 3, and 4
- Pfizer argued that 3 and 4 are not available as double patenting references because they issued after 1
  - Board disagreed, said what mattered was that 1 would expire after 3 and 4
  - But is this an “unjustified timewise extension”?
- Pfizer argued impermissible to rely on expressed preferences when the medical situation is such that the compounds of 2, 3, and 4 would present safety issues if orally administered
  - Board said that the specification can be used to determine what is claimed, and that is all that happened here; earlier filings relating to compounds of 2 and 4 suggested oral would be okay

## *Ex parte Pfizer (2010)*

- Result: Rejection for double patenting upheld
  - 102 rejections also upheld
- Impact: Double patenting can exist where later-filed applications grant as earlier-expiring patents whose claims anticipate those of the earlier-filed!
  - But couldn't the later-filed applications have been patentably distinct improvements? This possibility is not clearly addressed in the decision
  - Would the court have found double patenting if the later-filed applications also expired later? Should that really make a difference?
  
- Note: Favorably cited by Federal Circuit in *Gilead*

## So in summary...

- Earlier-filed application issues before but expires after later-filed application: DOUBLE PATENTING (*Pfizer*)
- Earlier-filed application issues before CIP-CON application is even filed, but still expires after CIP: DOUBLE PATENTING (*Martek*)
- Later-filed application issues before but expires after earlier-filed application: DOUBLE PATENTING (*Gilead*)
- CON of earlier-filed application is filed after later-filed application, but expires first: DOUBLE PATENTING (*Hubbell*)
- CON of earlier-filed application is filed after filing and issuance of later-filed application, but expires first: DOUBLE PATENTING (*Fallaux*)

## Relevance to today?

- Few pre-GATT patents are still alive
  - And where they exist, the damage is probably already done
- But initial applications sometimes receive long periods of PTA, sometimes years!
  - Will they suffer the same fate?
    - This rarely happens in continuations or divisionals
  - And what about PTE?

- So what are the lessons?
  - If you’ve filed “improvement” applications, be certain not to claim anything that might be deemed obvious over claims you get in any earlier-expiring “base” applications?
  - Should broad patents have only broad claims, avoiding “funneling”?
  - Can you get in trouble by filing continuations of an application that has racked up significant PTA?
  - Is there a risk that patent term extensions will get swept in?
  - Restriction requirements are your friend
  - Think twice before paying an issue fee
    - Check portfolio for existing or planned patents with longer terms and rationalize strategy
    - If you’re getting PTA, consider adding additional claims instead of filing a continuation



# Is Justice Being Served?

- Shouldn't the ultimate question of double patenting be "Is it unjust?"
- Why should a patentee have a harder time of it than an independent third party?
  - A patentee does stand to benefit from certain exemptions not available to outsiders
    - Disqualification of earlier unpublished patent filings as prior art
    - The one-year grace periods
  - But when a patentability isn't conditioned on one of these special privileges, what is the harm?
    - No one can assume that their actions will subject them only to one infringement suit
    - In a post-GATT world, the quid pro quo for patent term is priority claim – setting aside PTA and PTE, the former arguably just by definition, the latter long exempt from double-patenting concerns

# Is Justice Being Served?

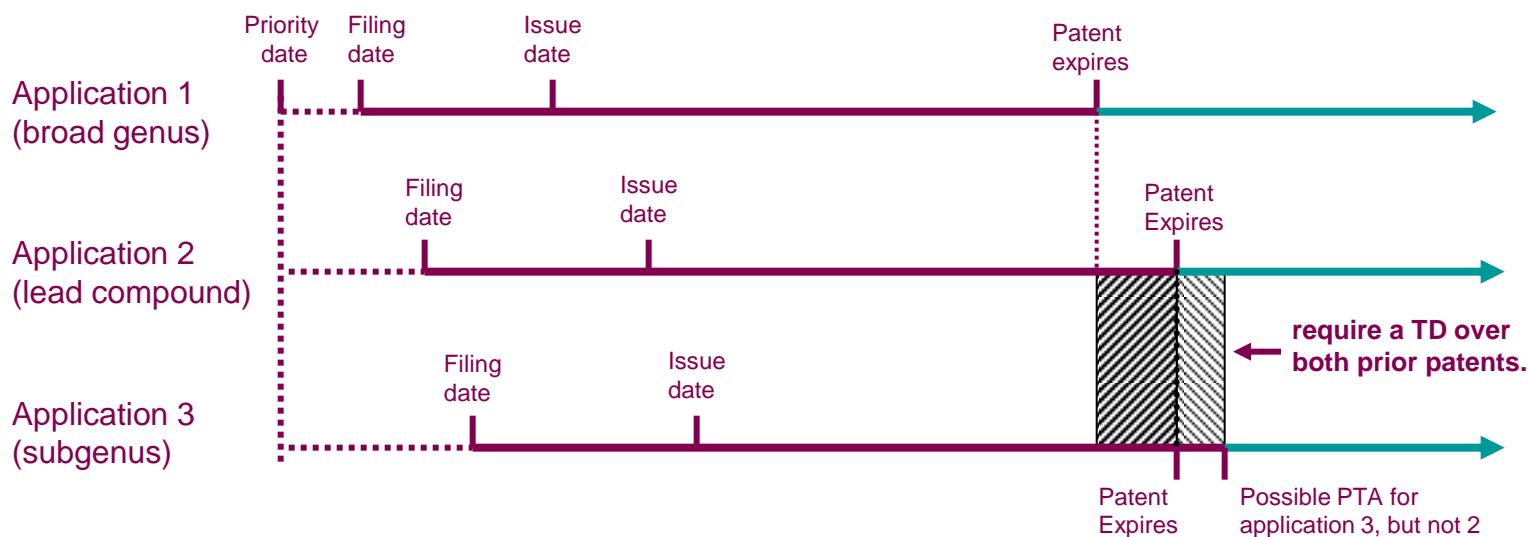
- Viewed through this lens, how do the cases turn out?
  - *Pfizer* – no double patenting (the pre-GATT patent term of the earlier patent is no less just because a later patent with a shorter term issues, even to an invention that is not patentably distinct)
  - *Martek* – no double patenting (same as Pfizer)
  - *Hubbell* – no double patenting (the ETH patents did not benefit from any special privileges)
  - *Fallaux* – unclear (if two-way test would succeed, probably no double patenting; but because applications were originally commonly owned, Vogels patents may have had advantage)
  - *Gilead* – arguable?
- Maybe typical common-inventor double patenting should fail, because the inventor has fewer privileges than an assignee would

## Real-Life Scenario

- A company screens molecules, identifies a genus of drug candidates, and files an application for the **genus** (**application 1**)
- Before this application publishes, the same inventors identify a **subgenus** including a few surprisingly efficacious compounds and a **lead compound** within this subgenus; the company files an application for the subgenus and the lead compound (**application 2**)
- The first application issues as a patent, and the claims of the second application are found patentable over the prior art, which under § 102(e) does not include the company's earlier patent
- The lead compound is not obvious over the claims of the patent
- However, the dependent claims of the earlier patent include a claim that arguably renders the subgenus obvious, and so an OTDP rejection is made
- For reasons unrelated to patentability, the company wants the lead compound to be the subject of its own patent, separate from the subgenus

# Scenario - Option One

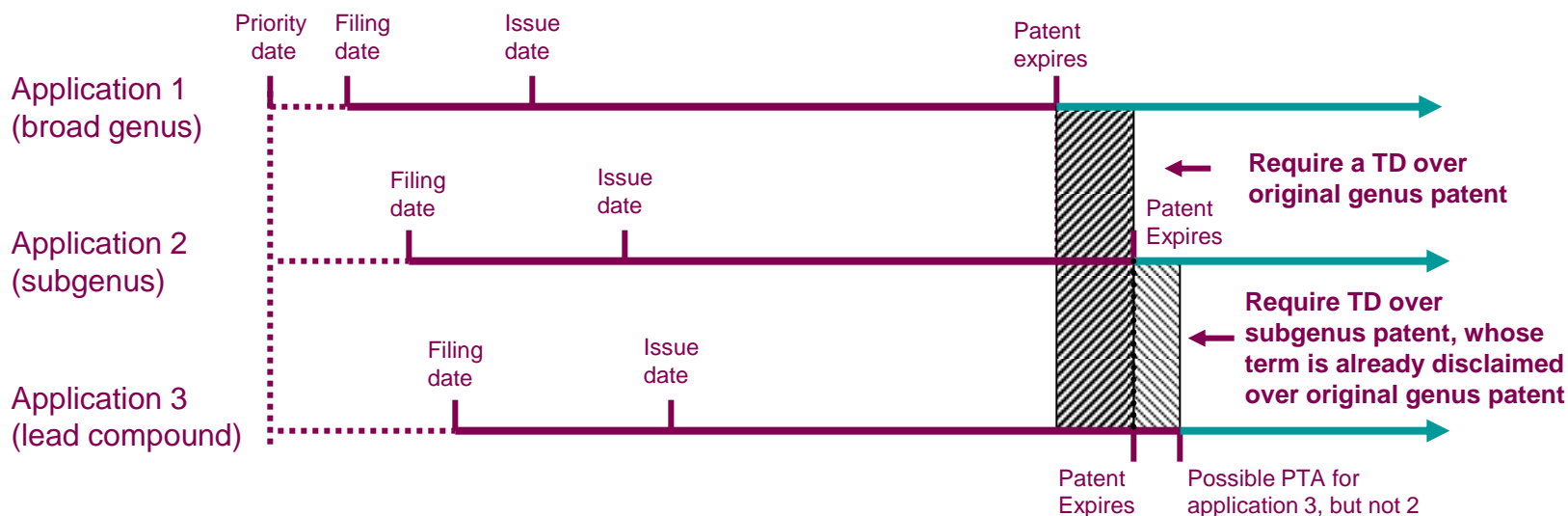
**Option One:** cancel claims to the subgenus from application 2, take the patent to the lead compound, and pursue the subgenus in a continuation (application 3)



- The term of the compound patent is unaffected, an obvious advantage
- The continuation will require a TD over both patents
- The examination of the continuation may not go as smoothly, putting the broader scope of the subgenus at risk

# Scenario - Option Two

**Option Two:** cancel claims to the lead compound from application 2, take the patent to the subgenus, and pursue the lead compound in a continuation (application 3)



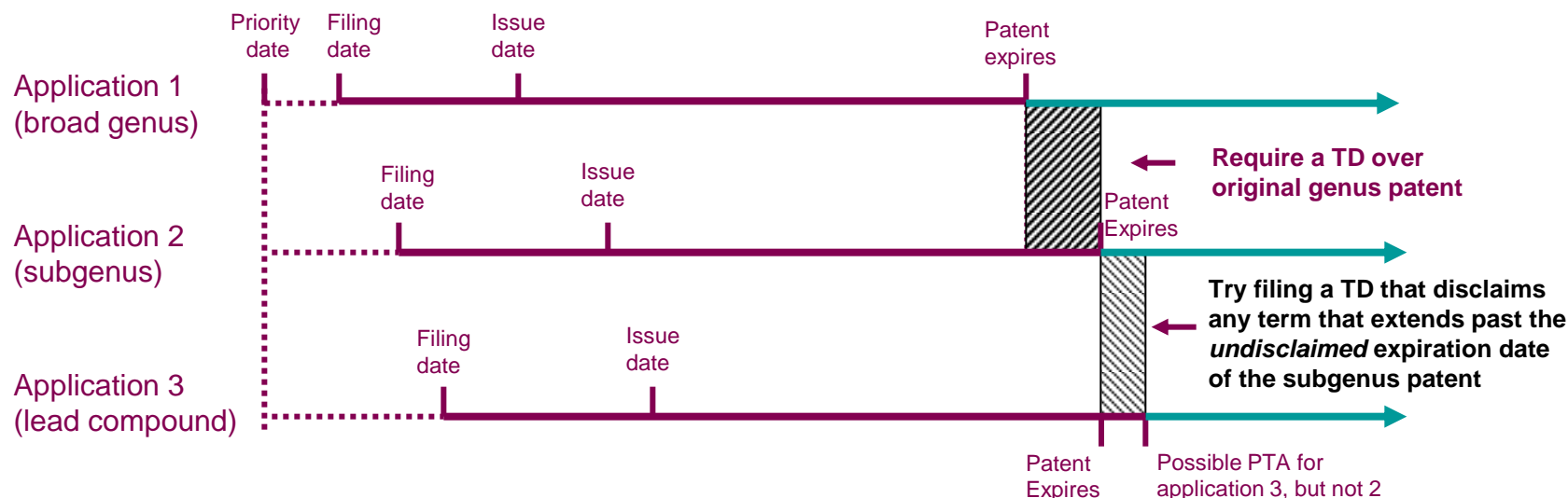
- The term of the compound patent will likely have to be disclaimed over the subgenus patent, whose term is already disclaimed over the original genus patent.
- A set of patented claims identical to those of option 1 would result, but the term for the compound is much shorter.

## Scenario - Option Two

- The asymmetry here arises from the provision of the USPTO's form TD that disclaims the term of a patent that extends past the expiration date of the earlier patent, *as the earlier patent may itself be terminally disclaimed over earlier patents*
- The equitable need for this indirect disclaimer is suspect, as it is not demonstrably unjust for the compound patent to last longer than the original genus patent

# Scenario - Alternative Strategies

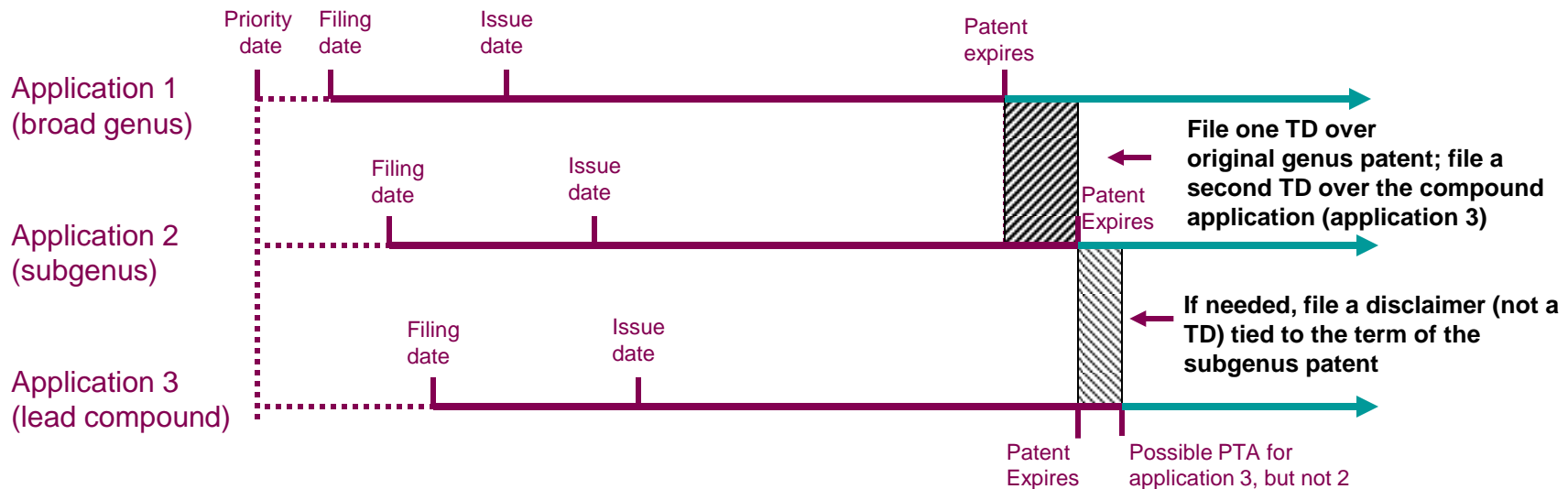
**Strategy I** : Follow option 2, but try to file a TD in compound application that, without referencing the original genus patent, disclaims any term that extends past the **undisclaimed** expiration date of the subgenus patent



- This tactic arguably achieves the dual goals of avoiding unjust extensions of patent term and risk of multiple lawsuits
- However, it may encounter hurdles in the USPTO or the courts

# Scenario - Alternative Strategies

**Strategy II:** Follow option 2, but respond to the double-patenting rejection in the continuation to the compound by filing a TD *in the subgenus patent* referencing the compound application



- The filing of a TD in the subgenus patent referencing the compound application would cement the requisite common ownership
- If a patent term adjustment (PTA) in the later compound patent would cause the term to exceed the undisclaimed term of the subgenus patent, a straightforward disclaimer - with no specific reference to the subgenus patent – should suffice
- This approach would avoid the arguably unnecessary indirect disclaimer over the original genus patent



# Thank You For Your Attention!



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