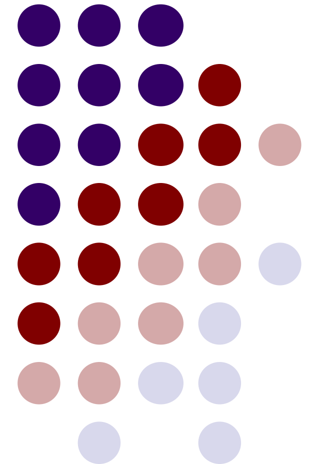
Federal Circuit Expands Double Patenting Doctrine



Gilead Sciences, Inc., v.

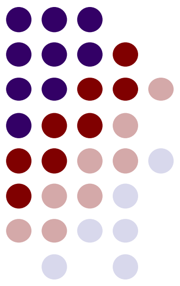
Natco Pharma Ltd.

(Fed. Cir. April 22, 2014)

Shawn Hamidinia

April 30, 2014

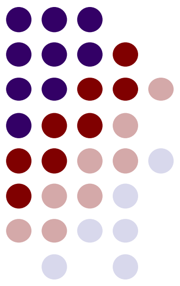
Overview



- Question Presented:

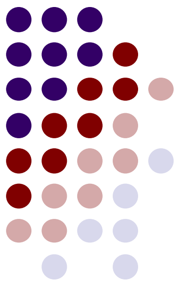
  Can a patent that issues *after* but expires *before* another patent qualify as a double patenting reference for that other patent?

Overview



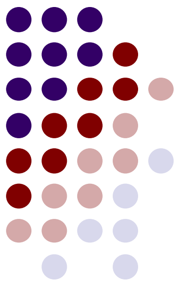
- U.S. District Court for the District of New Jersey held that it *cannot*.
- Federal Circuit reversed and remanded the case holding that *yes it can*.

Factual Background



- Gilead Sciences owns two patents, which are directed to antiviral compounds and methods for their use.
- Patents list same inventors.
- Specifications are substantially similar in content.
- Not part of the same family of patents.
- Not before the same Examiner.
- Different expiration dates.

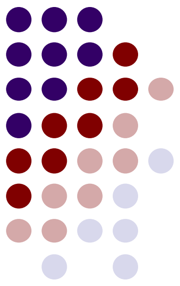
Factual Background



- Gilead's owns US Patent 5,763,483 ("the '483 Patent") and US Patent 5,952,375 ("the '375 Patent").

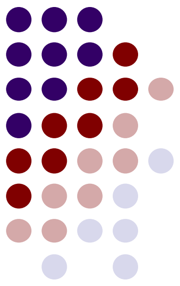
- The '375 Patent
  - Filed on February 26, 1996
  - Issued on September 14, 1999
  - Expires on February 27, 2015
  - Priority to regular application filed on February 27, 1995

Factual Background



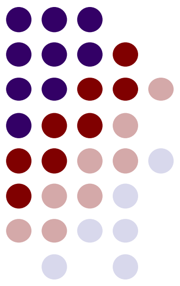
- The ‘483 Patent
  - Filed on December 27, 1996
  - Issued on June 9, 1998
  - Expired on December 27, 2016
  - Priority to provisional utility application filed on December 29, 1995

Factual Background



- After the ‘483 Patent issued, Gilead filed a terminal disclaimer in the application, which lead to the issuance of the ‘375 Patent.
- Thus, Gilead disclaimed any portion of the ‘375 Patent that extended beyond expiration date of ‘483 Patent.
- However, absent abandonment, this would not occur because the ‘375 Patent’s expiration date is before the ‘483 Patent’s expiration date.

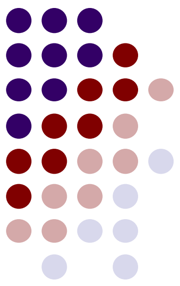
Factual Background

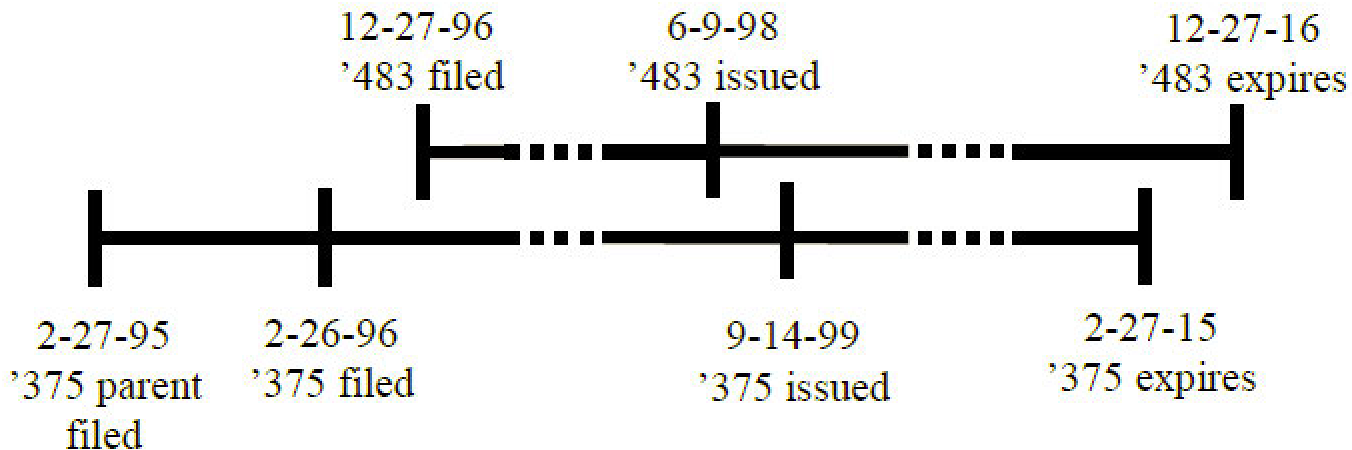


- Based on the prosecution history, it appears that this was the first time Gilead informed the patent Examiners of the existence of the other patent application.

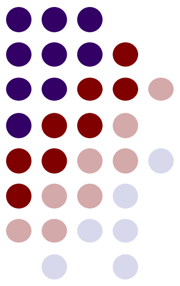
- No terminal disclaimer was filed for the ‘483 patent.

Relevant Dates for Each Patent



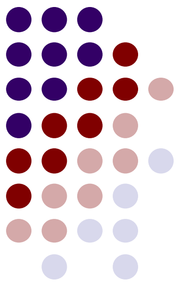


Litigation



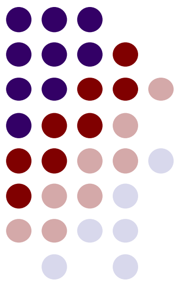
- Competitor Natco Pharma Limited (“Natco”) filed ANDA to market generic version of Gilead’s drugs covered by the ‘483 Patent.
- Asserted that the ‘483 Patent was invalid for obviousness-type double patenting over Gilead’s ‘375 patent (in light of claim 8 of the ‘375 Patent).
- Gilead sued Natco for infringement in March 2011.

Litigation



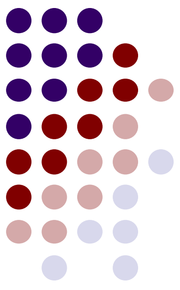
- Gilead argued that ‘375 Patent cannot serve as a double patenting reference against the ‘483 Patent because, even though the ′483 Patent’s expiration date is twenty-two months after the ′375 Patent’s expiration date, the ‘375 Patent issued after the ′483 Patent.

Litigation



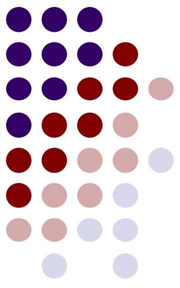
- Gilead argued that '375 Patent in no way extend the term of the exclusivity for the '483 Patent.
- Gilead tried to narrow the question to the potential term of extension for the '483 Patent (instead of the '375 Patent) because that patent issued first.
- Gilead cited to case law that limited double patenting bar to "second" or "later" issuing patents.

District Court’s Holding



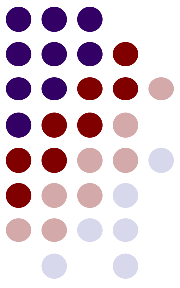
- Agreed with Gilead
  - U.S. District Court for the District of New Jersey granted Summary Judgment in favor of Gilead on Natco’s double patenting defense in December 2012.
  - District Court held that “a later-issued but earlier-expiring patent cannot serve as a double-patenting reference against an earlier-issued but later-expiring patent.”
    - Relied on two district court cases: *Abbott Labs v. Lupin Ltd.*, 2011 (D. Del. 2011) and *Brigham & Women’s Hosp. Inc. v. Teva Pharm. Inc.*, 761 F. Supp. 2d 210 (D. Del. 2011)

District Court’s Holding



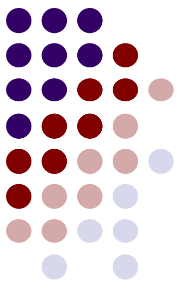
- The court also pointed to the Uruguay Round Agreements Act (URAA), which changed the length of a patent term for a U.S. patent from 17 from the patent issue date to 20 years from the earliest effective filing date.
- In the district court’s view, extensions of the patent term were not unlawful because the extensions were not a result of gamesmanship, but were a result of changes to the patent laws.
- Natco appealed.

Judicially-Created Doctrine of Obviousness-Type Double Patenting



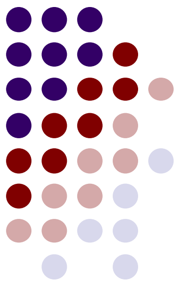
- Bar Against Double Patenting
  - Prohibits a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.
  - In exchange for patent, inventor must fully disclose invention and promise to permit free use at end of term.
  - The public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention.
  - Several sequential patents on the same invention would violate policy that patentee limited to one patent per term per invention.

Terminal Disclaimer at Issue



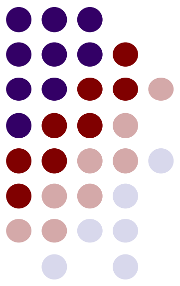
- ‘375 Patent expired on Feb 27, 2015. Thus, in the court’s view, the public should have the right to use the invention claimed in the Patent and all obvious variants of that invention.
- ‘483 Patent did not expire until Dec. 27, 2016
- ‘483 Patent extended the inventor’s term of exclusivity on obvious variants of the invention claimed for an additional 22 months past expiration of the ‘375 Patent.

Gilead’s Response



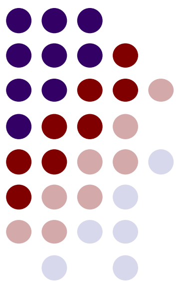
- The ‘375 Patent in no way extends the term of the exclusivity for the ‘483 Patent.
- Gilead argues that we should focus on the potential term extension for the ‘483 Patent instead of the ‘375 Patent because the ‘483 Patent issued first.
  - Gilead cites cases that describe the double patenting bar as applicable to the “later” issuing patent.

Federal Circuit



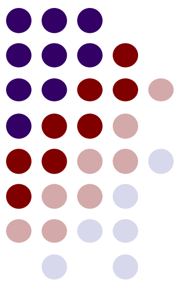
- The Federal Circuit responded by stating that the cases cited by Gilead dealt with patents to which the URAA did not apply, and to patents for which the expiration date was intertwined with the issuance date.

Federal Circuit's Holding

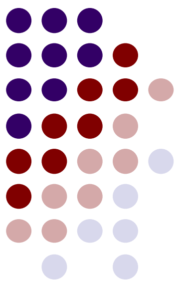


- Federal Circuit found risk that if issuance date was the determining factor for double patenting inquiries, post URAA patents could be subject to significant gamesmanship during prosecution.
  - Filing serial applications on obvious modifications of an invention,
  - Claiming priority to different applications in each, and
  - Then arranging for the application claiming the latest filing date to issue first.
- Thus, inventors could potentially obtain additional patent term exclusivity for obvious variants.

Federal Circuit's Holding

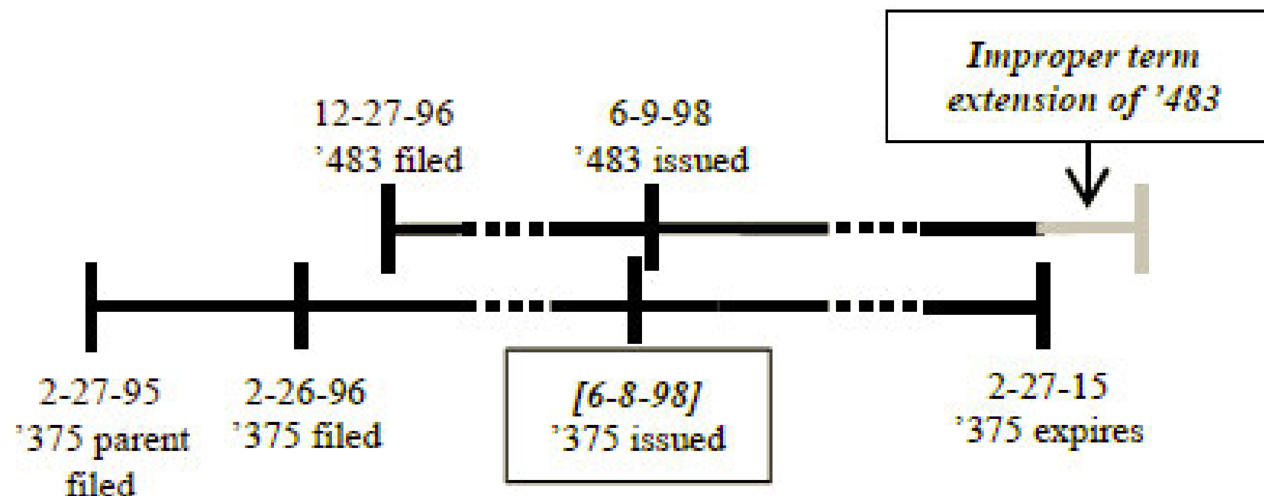


- Also, if the double patenting inquiry was determined by issuance date for post-URAA patents, there could be a significant difference in an inventor's period of exclusivity over his invention (and its obvious variants) based on mere days' difference in the issuance of several patents to the inventor.

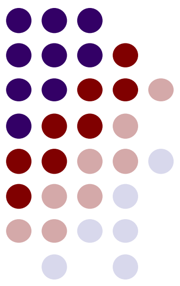


Federal Circuit’s Holding

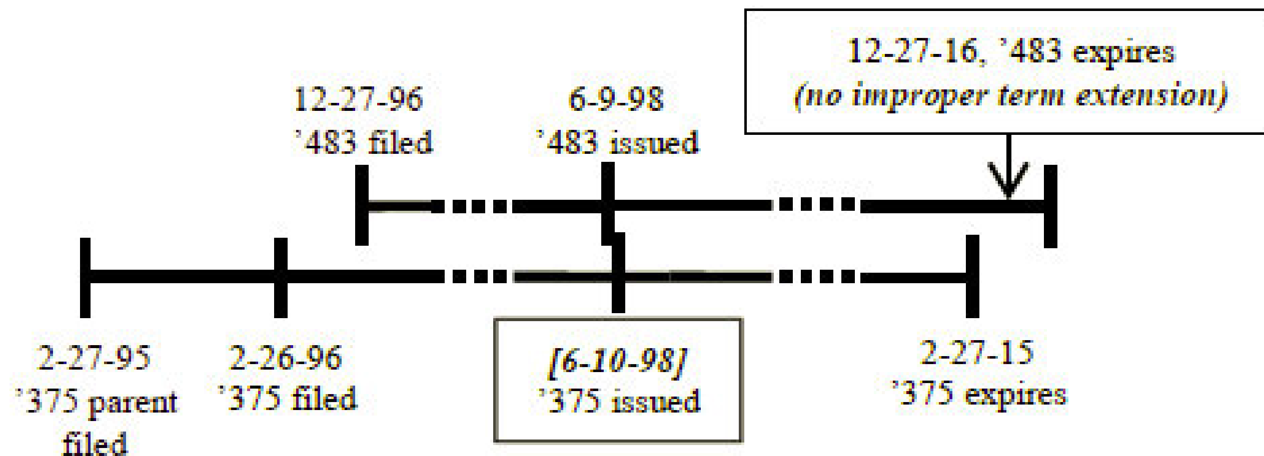
- For example, if the ’375 patent issued *the day before* the ’483 patent, in Gilead’s view, the last twenty-two months of the term of the ’483 patent would be an improper extension of patent term.



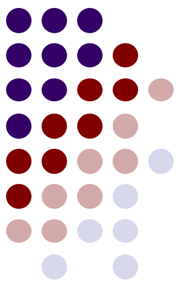
Federal Circuit's Holding



- If the '375 patent issued *the day after* the '483 patent, those last twenty-two months of the term of the '483 patent would not be an improper extension of patent term.

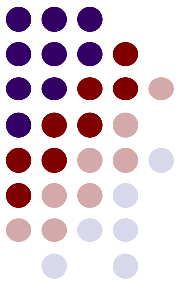


Federal Circuit's Holding



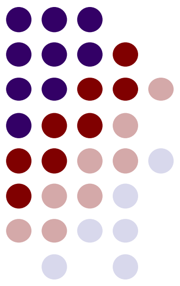
- Such significant vacillations in an inventor's period of exclusivity over his invention and its obvious variants is simply too arbitrary, uncertain, and prone to gamesmanship.
- Congress could not have intended to inject the potential to disturb the consistent application of the doctrine of double patenting by passing the URAA.
- Looking instead to the earliest expiration date of all the patents an inventor has on his invention and its obvious variants best fits and serves the purpose of the doctrine of double patenting.

Federal Circuit's Holding



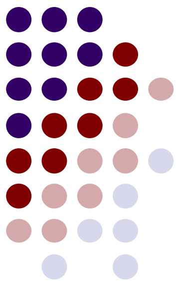
- Therefore, an earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent.
- A terminal disclaimer can preserve the validity of the later-expiring patent by aligning its expiration date with that of the earlier-expiring patent.

Dissenting Opinion



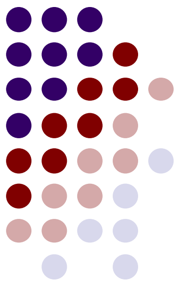
- Chief Judge Rader wrote the dissenting opinion.
- Found that judicially created doctrine of obvious-type double patenting was unnecessarily expanded by the majority opinion.
- Argued that successive continuations generally do not result in any additional patent term.
- Rather, the filing date of the earliest member of a patent family limits rest of related patents.

Dissenting Opinion



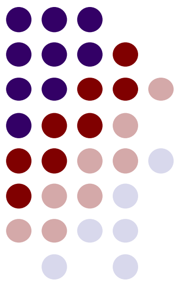
- Viewed majority opinion as crafting new rule to answer issue – that the expiration dates of patents govern, irrespective of the filing or issuance dates.
- Viewed majority opinion as impermissibly proscribing Gilead's patent rights by creating new rule when the later patent did not extend the term of its earlier patent.

Dissenting Opinion

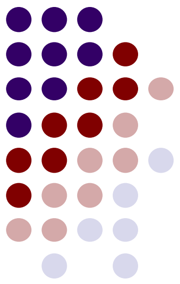


- Stated that the only relevant question is whether this court should extend the case law to encompass this new behavior exhibited by Gilead.
- Judge Rader did not perceive Gilead's conduct as so manifestly unreasonable to warrant a new judicially-created exception to invalidate patents.

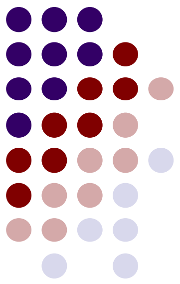
Discussion Points



- Was Gilead engaging in gamesmanship or was the lack of a Terminal Disclaimer in the ‘483 Patent an oversight?
- Did the court unnecessarily create a new caveat to this judicially created doctrine?
- Potential codification of the rule?
- What if difference in patent term is due to term adjustment or extension? Opinion does not address



Questions?



Thank you.