Double Patenting: Defeating Double Patenting Rejections and Avoiding Terminal Disclaimer

THURSDAY, JUNE 19, 2014

1pm Eastern  |  12pm Central  |  11am Mountain  |  10am Pacific

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DOUBLE PATENTING REJECTIONS

Donna M. Meuth
June 19, 2014
Eisai Inc.
DOCTRINE OF DOUBLE PATENTING

• To prevent the “unjustified extension of patent exclusivity beyond the term of a patent.”

• Expectation of public that upon the expiration of the patent it will be free to use the claimed invention and obvious modifications or variants.
Types:
• Same-invention.
• Obviousness-type.

Prohibition against double patenting applies to pre-AIA and AIA patent claims.
• Grounds for examiner rejection; and
• Grounds for allegation of invalidity in litigation.
• Not grounds for PGR according to PTAB because not a statutory basis for invalidity (See Apple Inc. v. SightSound Techs., CBM2013-00021, Paper 13, at 25 (Oct. 8, 2013)

Generally, can file a terminal disclaimer to overcome an obviousness-type double-patenting rejection.
Applications with all claims having an effective filing date before March 16, 2013.

- Double patenting rejection authorized where an applicant invokes the provisions of pre-AIA 35 U.S.C. §103(c) (joint research agreements), even though there is neither a common inventor nor a common patent owner.

- “[T]he application or patent and the subject matter disqualified under [amended] 35 U.S.C. 103(c)…will be treated as commonly owned for purposes of double patenting analysis. …This double patenting rejection may be obviated by filing a terminal disclaimer in accordance with §1.321(d).” 70 Fed. Reg. 54,261 (Sept. 14, 2005).
Applications with all claims having an effective filing date after March 15, 2013, and applications with mixed pre-March 16 and post-March 15 effective filing dates.

- Note: pre-AIA 35 U.S.C. §103(c) will not apply because according to AIA SEC. 3(n)(2), only pre-AIA §102(g) “crosses the line”

AIA §102(b)(2)(C) and §102(c) now apply to commonly-assigned and joint research inventions.

- Protection will only shield the prior effectively filed invention from being considered as §102(a)(2) prior art against the later invention, but will, under those limited circumstances, shield the later invention from both novelty and obviousness attack.
- But that protection may not shield later invention from obviousness double-patenting over earlier.
Anticipation type ("same-invention" double patenting)
• No requirement that the first patent disclosure qualify as "prior art", but requirement for identity of claimed subject matter makes it analogous to anticipation.
  • But a species anticipates a genus under §102, and in double patenting, the species and genus are not the same invention.

Obviousness-type double patenting
• Prohibits claims in a second patent or application that are not patentably distinct from claims in a first patent.

Provisional v. actual rejections
• Actual ODP rejection - to a pending application in view of a first issued patent or in view of another pending application.
• Provisional ODP rejection in view of a pending application when there are two pending applications by the same inventor or assignee claiming conflicting subject matter.
  • See MPEP §804 (2000).
The distinctions between obviousness under 35 U.S.C. §103 and nonstatutory double patenting include:

- The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;

- Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;

- Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.
**DOUBLE PATENTING**

- Geneva v. GSK (con’t)

**Original GSK patent filed April 17, 1975**

PTO restriction requirement

- patents granted in 1985*
- patents granted in 2000/01*

*No terminal disclaimers filed*
Geneva v. GSK (con’t)

- Patents relate to antibiotic clavulanic acid and its salts
  - 1985 patents
  - 2000/01 patents

- DC: granted SJ that 2000/01 patents invalid due to double patenting
  - Original application did not show a PTO-issued restriction requirement
    - No §121 shield

- FC: Affirmed.
  - If the claims are changed “in material respects” from the claims subject to the restriction requirement, there is no consonance and §121 will not provide any protection from a charge of double patenting.
OBVIOUSNESS AND DOUBLE PATENTING


• Obviousness under § 103 and obviousness-type double patenting are analogous, but not identical.

  • The patent principally underlying the double patenting rejection need not be prior art.

  • In “obviousness-type double patenting in cases involving claimed chemical compounds, … the analysis must necessarily focus on the earlier claimed compound over which double patenting has been alleged, lead compound or not.”
Otsuka (con’t)

• FC: Asserted claims are not invalid for nonstatutory double patenting.

  • Geneva v. GSK footnote: “[o]bviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not.”

  • “Geneva, however, involved nonstatutory double patenting based on anticipation, not obviousness. …For anticipation, of course, motivation in the prior art is unimportant. …neither Geneva nor Procter & Gamble stands for the proposition that, in considering whether one compound is an obvious variant of another for purposes of nonstatutory double patenting, analyzing the compound of the prior claim for a reason or motivation to modify is irrelevant.”
NO MOTIVATION TO CHANGE PRIOR ART

Otsuka (con’t)

• FC:

  • “the prior art... did not teach the person of ordinary skill in the art to pursue a 2, 3–dichloro substitution on the phenyl ring to achieve antipsychotic activity.”

  • Evidence demonstrated “the high degree of unpredictability in antipsychotic drug discovery as of the priority date…and that antipsychotic research at that time was “notoriously unsuccessful,”
DOUBLE PATENTING

Sun Pharmaceutical Industries, Ltd. v. Eli Lilly and Co., 611 F.3d 1381 (Fed. Cir. 2010), cert. denied, 131 S.Ct. 2445 (U.S. May 16, 2011))

Original application filed March 10, 1983 described only gemcitabine’s utility for antiviral purposes

‘826 patent (Separate invention filed December 4, 1984, issued Nov 7, 1995) added description of gemcitabine’s anticancer utility to spec; no term disclaimer. Double patenting alleged over earlier-issued ‘614 patent

‘614 patent issued Feb 28, 1989 gemcitabine and method for using to treat viral infections; from divisional CIP filed December 4, 1984 adding one paragraph regarding anticancer utility
Sun v. Eli Lilly (con’t)

- Lilly’s patents covering gemcitabine (Gemzar®)

- FC: Affirmed claims invalid for double patenting.
  - The “earlier patent claimed a compound, disclos[ed] its utility in the specification, and a later patent claimed a method of using the compound for a use described in the specification of the earlier patent.”
Eli Lilly v Teva Parenteral Medicines, Inc., 689 F.3d 1368 (Fed. Cir.), reh’g denied (Nov. 2012)

Teva: ’932 patent claims invalid for obviousness-type double patenting over new antifolate compound claim of ’608 patent and intermediate claimed in ’775 patent.

DC: no double-patenting.
Lilly v. Teva (con’t)

- FC: Affirmed. Differences cannot be considered in isolation - analysis is of claim as a whole.

  “the district court did not err by examining whether one of ordinary skill in the art would have been motivated to modify the ’608 Compound to create pemetrexed, considering the compounds as a whole.”
Lilly v. Teva (con’t)

- FC: (con’t)
  - As for the intermediate, “The focus of the obviousness-type double patenting doctrine thus rests on preventing a patentee from claiming an obvious variant of what it has previously claimed, not what it has previously disclosed. ...Rather than a composition and a previously disclosed use [as in Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373 (Fed. Cir. 2003) and Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 518 F.3d 1353 (Fed. Cir. 2008)], the claims at issue recite two separate and distinct chemical compounds: the ’775 Intermediate and pemetrexed, differing from each other in four respects. That alone suffices to undermine Teva’s argument regarding the ’775 Intermediate, for the asserted claims of the ’932 patent do not recite a use of the same compound, but a different compound altogether.”
CAN AN EARLIER-ISSUED PATENT BE REJECTED FOR OTDP?

- Policy reason for ODP

“[ODP] prohibit[s] 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….”

CAN AN EARLIER-ISSUED PATENT BE REJECTED FOR OTDP?  **YES**

**Ex parte Pfizer Inc., 2010 WL 532133, *21**  
(B.P.A.I. Feb 2, 2010)

- **Held**: “it is the patent term and not the patent issue date that determines if” OTDP applies to the genus patent in view of the species patents

- “[t]he rule against double patenting seeks to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about”

- Held: “the later-filed and later-issued [species] patent could not and did not create an ‘unjustified time-wise extension’ of the earlier filed, earlier issued [genus] patents”

- “Of course, had the [species] patent issued before the [genus] patents, the [species] patent would have anticipated and invalidated the [genus] patents [based on ODP]”
CAN AN EARLIER-ISSUED PATENT BE REJECTED FOR ODP?  **NO**


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<th>Issue date</th>
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- **Held:** Abbott has obtained no timewise extension of the earlier-issued but later-expiring ‘428 patent through the ‘930 patent; the term of the ‘428 patent is the same as it would have been had the ‘930 patent never issued.

- The Court concluded that Chief Judge Bartle’s decision is persuasive and properly resolves the dispute at bar: “Chief Judge Bartle held that a later-issued but earlier-expiring patent could not serve as a double-patenting reference against two earlier-issued by later-expiring patents, explicitly rejecting Pfizer.”
Federal Circuit Weighs in with Gilead

- **Gilead Sciences, Inc. v. Natco Pharma Ltd., --F.3d __** (Fed. Cir. April 22, 2014)
  - Gilead’s U.S. Pat. Nos. 5,763,483 and 5,952,375 commonly-owned, list same inventors, similar written descriptions, BUT do not claim priority to a common patent application and have different expiration dates.
  - Natco: ’483 patent was invalid for obviousness-type double patenting over ’375 patent.
  - Gilead: ’375 patent cannot serve as a ODP reference against the ’483 patent.
Federal Circuit Weighs in with Gilead

- **Gilead (con’t)**
  - DC: Judgment of infringement.
    - “a later-issued but earlier-expiring patent” cannot “serve as a double-patenting reference against an earlier-issued but later-expiring patent.”

- FC: Vacate and remand.
  - “Can a patent that issues after but expires before another patent qualify as a double patenting reference for that other patent?...under the circumstances of this case that it can[.]”
  - “it is a bedrock principle of our patent system that when a patent expires, 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. ...And that principle is violated when a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention claimed in that patent because the inventor holds another later-expiring patent with claims for obvious modifications of the invention. Such is the case here.”
Federal Circuit Weighs in with Gilead

• Gilead (con’t)
  – Why?
    • When the ’375 patent expired, “the public should have the right to use the invention claimed in the patent and all obvious variants of that invention.”
    • But the ’483 patent does not expire until December 27, 2016, “and it (we assume for this appeal) covers obvious modifications of the invention claimed in the ’375 patent.” The ’483 patent, therefore, extends the inventors' term of exclusivity on obvious variants of the invention claimed in the ’375 patent for an additional twenty-two months past the expiration of the ’375 patent. That plainly violates the public's right to use the invention claimed in the ’375 patent and all obvious variants of it after the ’375 patent expires.

• Not important that the ’483 patent issued first.
• Gilead cited later-issuing patent cases that dealt with patents to which the URAA did not apply; the patent term of the later-issued patent was appropriate because before the URAA, later issued patents expired later.

• Now, a patent can issue first does not expire first, so the patent expiration dates should control, not issuance dates.
Federal Circuit Weighs in with Gilead

Federal Circuit’s 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 Weighs in with Gilead

Federal Circuit’s example “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.”
“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.”
Judge Rader Dissent

• Gilead dissent (con’t)
  – Court’s new rule expanding the judicially-created doctrine of obviousness-type double patenting “unwarranted”

  – No reason to apply double patenting
    • does not raise the policy concern regarding subsequent extensions of patent term;
    • this case does not involve the potential for harassment by multiple assignees asserting essentially the same patented invention.

  – “Instead of claiming priority to the ’375 patent family, Gilead filed the application that ultimately issued as the ’483 patent as a separate family. In the process, Gilead gave up roughly 10 months of priority. Consequently, the ’483 patent is subject to roughly 10 months of intervening prior art. Nevertheless, despite sacrificing almost a year of priority, the court contends that Gilead acted improperly by continuing to pursue claims in the application that issued as the ’375 patent.”
• Gilead dissent (con’t)

  – “it is more accurate to say that upon expiration of a patent, that particular expired patent is no longer a bar to the public's use of the claimed subject matter.”

  – “the only relevant question is whether this court should extend our case law to encompass this new behavior exhibited by Gilead… I do not perceive Gilead's conduct as so manifestly unreasonable to warrant a new judicially-created exception to invalidate patents.”

  – “Under the AIA's new ‘first-inventorto-file’ framework, prospective patentees are under tremendous pressure to file their applications early. I am concerned that today's opinion will have unforeseen consequences in this new race to the Patent Office.”
What Does This Mean for Practitioners?

- Broader scope of double-patenting doctrine
THANK YOU!

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Pre-AIA: Common Ownership Problem

- A and B work for company X
- A and B have a duty to assign all inventions to company X

- A comes up with an invention
  - Assigned to X
- A and B later come up with another invention
  - Assigned to X

- A and A+B are considered different persons for determination of availability of A invention as prior art
• 1984 Amendment to §103:
  – “Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.”

• 1999 Amendment extended to prior art qualifying under Section 102(e)
Pre-AIA: JRA Collaboration Problem


- Background
  - Oddzon sued Just Toys for patent infringement; Just Toys alleged patent invalidity
    - Invention created by researchers from more than one organization
    - Two confidential designs disclosed between researchers at the separate organizations

  - Question: Can confidential information shared between the members of a research team be prior art for the purpose of rendering that invention obvious under § 103?
Federal Circuit held:

– Confidential information exchanged between research partners is available as prior art to invalidate a patent
– Except if rights to the invention were assigned to a single entity before creation of that invention

Practical effect

– Inventions developed through a structured joint research agreement could be rendered unpatentable because parties at separate organizations had collaborated and exchanged information
Pre-AIA: Solution to the JRA Collaboration Problem

• 2004 Cooperative Research and Technology Enhancement Act ("CREATE"):
  – Extended safe harbor beyond only common ownership to joint research agreements
  – Only for 103 rejections based upon prior art qualified under 102 (e), (f), or (g)
Post AIA: Solutions to the Common Ownership Problem

- **Common Ownership Protection Moved from § 103 to § 102**
  - 102(b)(2)(C): U.S. patent filing is not prior art if commonly owned with claimed invention
  - Only an exception to 102(a)(2)
    - U.S. patents, U.S. patent application publications, or WIPO published applications effectively filed, but not published, before the effective filing date of the claimed invention
  - Not an exception to 102(a)(1) (published prior to filing date)
  - Deadline for common ownership – effective *filing date* of claimed invention

- **CREATE Act provisions (joint development agreements) moved to §§ 100, 102**

- Common ownership protects against anticipation as well as obviousness rejections (but not against obvious-type double patenting rejections)
• § 102(c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—

   - Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—

     1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;

     2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

     3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.
Limitations of §102(b)(2)(C) Exception

Common Ownership Protection

- §102(b)(2)(C) exception does not remove a §102(a)(1) prior art, or a double-patenting rejection, or a lack of enablement rejection - a “document need not qualify as prior art to be applied in the context of double patenting or enablement.” See pp. 11080 of Examination Guidelines (2/14/13).
• § 1.104 Nature of examination.
  – (c) * * *
    • (4)(i) Subject matter which would otherwise qualify as prior art under 35 U.S.C. 102(a)(2) and a claimed invention will be treated as commonly owned for purposes of 35 U.S.C. 102(b)(2)(C) if the applicant or patent owner provides a statement to the effect that the subject matter and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.
How To Show JRA Under §102(b)(2)(C)

- §1.104 Nature of examination.
  - (4) (ii) Subject matter which would otherwise qualify as prior art under 35 U.S.C. 102(a)(2) and a claimed invention will be treated as commonly owned for purposes of 35 U.S.C. 102(b)(2)(C) on the basis of a joint research agreement under 35 U.S.C. 102(c) if:
    - (A) The applicant or patent owner provides a statement to the effect that the subject matter was developed and the claimed invention was made by or on behalf of one or more parties to a joint research agreement, within the meaning of 35 U.S.C. 100(h) and §1.9(e), that was in effect on or before the effective filing date of the claimed invention, and the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
    - (B) The application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.
• “A clear and conspicuous statement by the applicant … that the claimed invention of the application under examination and the subject matter disclosed in the … (prior art) … were owned by the same person or subject to an obligation of assignment to the same person not later than the effective filing date of the claimed invention will be sufficient to establish that the AIA 35 U.S.C. 102(b)(2)(C) exception applies. … The applicant may present supporting evidence such as copies of assignment documents, but is not required to do so. Furthermore, the Office will not request corroborating evidence in the absence of independent evidence which raises doubt as to the veracity of such a statement. The statement under AIA 35 U.S.C. 102(b)(2)(C) will generally be treated by Office personnel analogously to statements made under pre-AIA 35 U.S.C. 103(c).”

See pp. 11080 of Examination Guidelines (2/14/13).
Consequences of AIA §102(b)(2)(C): Alteration in Chronology

• May allow inventor to proactively take care of potential §102(a)(2) or §§ 102(a)(2) / 103 problem by obtaining prior art or a JRA before filing, not before the time the invention was made

• Likewise, obtaining prior art or a JRA before filing may provide a basis for filing a terminal disclaimer to overcome a double patenting rejection
§ 102(c) says it shall be deemed to be owned by the same person or subject to an obligation of assignment if the subject matter claimed was developed under a JRA before the effective filing date of the claimed invention. See also §102(b)(2)(c) (common ownership exception to §102(a)(2)) and § 102(c) allows folding JRA into §102(b)(2)(C)

• **Big change!!** Old law was “at the time the invention was made”
Common Ownership Questions

• What happens when there is no common ownership?
  – A invents and assigns to company X
  – A then moves, and A and B invent and assign to company Y

• This is an issue often faced by Academic Research Institutions
  – Companies should also be aware of complications of this issue, and potential double patenting issues
• First scenario:
  – A’s application is published less than one year prior to effective filing date of A+B’s application
  – 102(a)(1) applies

• Exception 102(b)(1)(A)
  – The disclosure was made by the inventor or joint inventor or by another who obtained the subject matter directly or indirectly from the inventor or joint inventor
Common Ownership Questions

• Second scenario:
  – A’s application is not published prior to effective filing date of A+B’s application

• Exception 102(b)(2)(A)
  – The subject matter disclosed was obtained directly or indirectly from the inventor or joint inventor
  – Different inventive entity is not an issue
• So even without common ownership or a joint research agreement, the application of A may not be available as prior art against the application of A+B as long as A’s invention was not publicly disclosed more than a year prior to A+B’s effective filing date
• What about double patenting?
  – MPEP § 804(I)(A): "Double patenting may exist between an
    • issued patent and an application filed by the same inventive entity, or
    • by a different inventive entity having a common inventor, and/or by a common assignee/owner."
• If at least one of A+B’s claims is not patentably distinct from an issued claim in A’s patent then A+B’s application is subject to a double patenting rejection, even though A’s patent is not available as prior art.

• See In re Hubbell, No. 2011-1547 (Fed. Cir. 2013).
Hubbell asked:

- Does obviousness-type double patenting (“OTDP”) apply where an application and a conflicting patent have one or more inventors in common, but the inventive entities are not identical and the applications were never commonly owned?
- Can a terminal disclaimer be filed to overcome OTDP in the absence of common ownership?
- Should a two-way obviousness test apply to overcome OTDP?
• Background:
  – Inventors Hubbell and Schense at CalTech
    • research resulted in ’509 application (earliest priority April 3, 1997)
    • assigned to CalTech
  – Hubbell and Schense left CalTech to join ETHZ
    • research resulted in ’685 patent (earliest priority August 27, 1998)
    • Assigned to ETHZ and Universitat Zurich
• Background:
  – ’685 patent is not available as prior art under §§ 102 or 103 to the ’509 application
  – Examiner rejected ’509 application based on OTDP over ’685 patent
  – BPAI agreed, finding claims of ’685 patent (species claims) anticipated representative claim of ’509 application (genus claim)
  – Hubbell appealed
• Court held:
  – Agreed with BPAI, rejecting Hubbell’s argument that OTDP should never be applied in the absence of common ownership
  – Cited *In re Fallauz*, 564 F.3d 1313, 1315 (Fed. Cir. 2009): OTDP is meant to prevent harassment of an alleged infringer by multiple assignees asserting essentially the same patented invention
  – No JRA, so terminal disclaimer not available
  – No 2-way obviousness analysis: Hubbell partially responsible for delay that caused ’685 patent to issue first
Parties should evaluate consequences of a terminal disclaimer pursuant to a JRA

- Can overcome rejection based on OTDP
- BUT might lead to complications with enforcement

37 C.F.R. 1.321(d)(3) – a terminal disclaimer in the context of a JRA must:

- “Include a provision waiving the right to separately enforce any patent granted on that application … and the patent … which formed the basis for the double patenting … and that any patent granted on that application … shall be enforceable only for and during such period that said patent and the patent … which formed the basis for the double patenting are not separately enforced”
Consequences: JRA Terminal Disclaimers

• What this means for you?
  – JRA-related terminal disclaimers may greatly complicate patent enforcement issues
  – Unless certain patents always enforced together, terminally-disclaimed patents no longer enforceable
  – Potential issues with, e.g., platform technology patents

• What steps to take?
  – Evaluate prosecution strategy, and have a plan
  – Coordinate regarding the filing of any JRA-related terminal disclaimers
  – Separate enforceability could be issue with potential licensees (who controls enforcement?)
Conclusions

- Be aware of common ownership issues:
  - Inventors move, important to be aware of prior applications/patents with common inventors
    - Both an upstream and downstream concern
    - Track prosecution of relevant applications/patents
    - Do not delay, and be thoughtful about order in which species versus genus claims are prosecuted
  - Under AIA, §102(a)(2) or §§ 102(a)(2) / 103 problem may be removed by obtaining prior art or entering JRA before filing
  - But be aware of enforcement issues raised by JRA terminal disclaimers
Thank You!

Margaret Sampson
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B-Delay Possibilities

Tom Irving
Patent Term Adjustment and AIA

• AIA SEC. 9: A patentee’s challenge to the USPTO’s PTA calculation that is filed on or after September 16, 2011, must be filed with the U.S. district court for the Eastern District of Virginia ("ED VA"), instead of the U.S. district court for the District of Columbia ("D DC").
Patents Eligible for PTA

• 37 C.F.R. §1.702 Grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, filed on or after May 29, 2000).

• 37 C.F.R. §1.701 Extension to patent term for examination delay for utility patent applications filed on or after June 8, 1995, and before May 29, 2000.

• 79 Fed. Reg. 27,755 (May 15, 2014)
  • The amendments to 37 CFR 1.702, 1.703, and 1.705 apply to any patent granted on or after January 14, 2013. The amendment to 37 CFR 1.704 applies to any application in which a notice of allowance was mailed on or after April 1, 2013.
  • The optional procedure for requesting a patent term adjustment recalculation applies only to patents issued between January 14, 2013, and May 20, 2014, that resulted directly from international applications, and the request must be filed no later than July 31, 2014.
B-Delay Possibilities

35 U.S.C. § 154(b):

- Provides PTA should certain USPTO actions take longer than decreed periods of time
  - Guarantee of prompt USPTO responses ("A-Delays")
  - Guarantee of no more than 3-year application pendency ("B-Delays")
  - Guarantee of adjustment for delays due to interferences, secrecy orders, and appeals ("C-Delays")

- Adjustments are day for day for the amount of delay
B-Delays
Guarantee of No More Than 3-Year Application Pendency

B-Delays occur if the USPTO does not:
• Issue a patent within 3 years of the actual filing date

But B-Delays do not include:
  – time after request for continued examination (RCE)*
    • Note Exelixis I, Exelixis II, and Novartis cases
  – time consumed by an interference
  – time consumed by imposition of a secrecy order
  – time consumed by PTAB or Federal court review
  – any delay at the request of the applicant
Calculating Patent Term Adjustment

• Under 37 C.F.R. § 1.703(f), PTA is calculated by:
  
  — Adding any A-Delays, B-Delays and C-Delays together

  — Subtracting any overlap between A-Delays, B-Delays and C-Delays
    • Overlap is calculated by counting delays occurring on the same calendar days
      — Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010)
      — Before Wyeth, USPTO interpreted statute as only allowing greater of A-delays or B-delays, not both

  — Subtracting any applicant delays
Jan. 15, 2014
The Federal Circuit


  • Vacate and remand.

  • "We address those two interpretations in our decision today in Novartis AG v. Lee, No. 13-1160 (Fed. Cir. Jan. 15, 2014). Based on the ruling in Novartis, we vacate the judgments as to patent term adjustment for the ‘436 and ‘622 patents in this case and remand for redetermination of the proper adjustments in accordance with Novartis.”
Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. 2014)

PTA determination (reversed-in-part)

- “no adjustment time is available for any time in continued examination, even if the continued examination was initiated more than three calendar years after the application’s filing.”

- “the patent term adjustment time should be calculated by determining the length of the time between application and patent issuance, then subtracting any continued examination time (and other time identified in (i), (ii), and (iii) of (b)(1)(B)) and determining the extent to which the result exceeds three years. Such a reading ensures that applicants recover for any ‘delay[s] due to the failure of the [PTO],’ without allowing the applicant to recover for ‘any time consumed by continued examination,’ as the statute requires. Id. § 154(b)(1)(B)(i).”

Jan. 15, 2014
The Federal Circuit
Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. 2014)

“...the correct interpretation of the statute is the PTO’s view that time spent in a continued examination does not deplete the PTO’s allotment of three years for application processing before a resulting patent has its term extended, no matter when the continued examination begins.”
Affirmed Time After Allowance Until Issuance Should Be Counted

- **Novartis AG v. Lee**, 740 F.3d 593 (Fed. Cir. 2014)

- “While we thus disagree with Novartis on its first § 154(b)(1)(B) issue, we agree with Novartis on its second § 154(b)(1)(B) issue. ...We reject the PTO’s view that the time after allowance, until issuance, is ‘time consumed by continued examination’ and so is excluded from adjustments given to the patentee. Such time from allowance to issuance undisputedly would count toward the PTO’s three-year allotment in a case not involving a continued examination. There is no basis for distinguishing a continued examination case.”

- “In the present case, time after allowance was not time caused by the continued examination. Because the PTO applied the contrary view in calculating the patent term adjustment for the ‘155, ’518, and ’631 patents, those calculations must be corrected.”
TIME FROM ALLOWANCE TO ISSUE...

• Federal Circuit in Novartis: time excluded from B-delay for filing a RCE > 3 years after filing ends at allowance, not the issue date.
  • “allowance-to-issuance time is not to be distinguished according to whether there is a continued examination in a prosecution. Either way such time is plainly attributable to the PTO.”

• Where PTA did not include days between allowance and issuance, file request that the time from allowance to issue be included in B-delay.
  • As pointed out by Susan J. Mack and Azy S. Kokabi, Sughrue Mion PLLC in IPLaw 360 article, “Calculating Patent Term Adjustment Post-Novartis” (Feb. 13, 2014): for patents issuing on or after Jan. 14, 2013, all applications for PTA must be filed within seven months of the issue date (two months from the grant of the patent plus an additional five months with payment of extension of time fees).
  • Novartis decision Jan. 15, 2014, so includes any patent issuing on or after June 15, 2013.
Hypothetical in Light of Gilead

- Earlier-issued genus patent (with PTA), later-issued species patent.
- Does Gilead require filing a TD in the genus based on a later-issued species patent?
- Does In re Berg, 140 F.3d 1428 (Fed. Cir. 1998) provide a counter-argument?
  - species issued first so had to file TD in genus.
  - Court suggested to file all claims in one application.
- Another option, prosecute genus claims first and delay issuance of species claims.
Maximizing PTA: Avoiding Pitfalls

• Respond within 3 months of an action – don’t take extensions.
  • 37 C.F.R. §1.704(b): >3 months is “failure to engage in reasonable efforts to conclude processing or examination” and will mean deduction from PTA.
  • Respond right at end of 3 months??

• Make a telephone election
  – A written restriction requirement is a first action and will stop the 14-month clock
  – A first office action usually takes longer to prepare

• File electronically, by Express Mail or FAX
  – If mailed by first class, clock runs until response is received in the USPTO, even if includes a certificate of first class mailing
  – Mail delays can end up amounting to weeks of lost PTA

• Consider filing a CIP rather than a Continuation
  – First action for a CIP typically takes longer than for a Continuation
Maximizing PTA: Avoiding Pitfalls

• Do not file papers after allowance
  – Ask examiner to make corrections by examiner’s amendment
  – If a problem can be corrected by certificate of correction, wait and file after patent issues

• Avoid Terminal Disclaimers
  – PTA cannot overcome a terminal disclaimer
  – Try to ensure a patent with PTA issues first

• Avoid Requests for Continuing Examination
  – Filing an RCE cuts off any further B-Delays?
    *Subject to discussion of Exelixis I/Novartis (see slides infra)

• Be aggressive and argue against or appeal final rejections
  – Try to keep prosecution open without filing an RCE
Maximizing PTA: Avoiding Pitfalls

• Make sure replies are complete and do not have an omission
  – PTA is lost for time needed to correct the omission
  – Supplemental replies result in the same loss as an omission
    • Days are counted from the day after the reply with omission was filed, not the date the reply was due
  – Ask examiner if the problem can be corrected in the next reply or by an examiner’s amendment

• Timely file Information Disclosure Statements (IDS)
  – File an IDS before the first office action or with a reply
    • Not considered untimely if IDS is filed within 30 days of a communication from the USPTO or a foreign patent office with a certification under 37 C.F.R. § 1.704(d)
      – Earlier rule only included foreign office communications
      – Certification under 37 CFR § 1.97(e)(1) does not prevent loss of PTA (within 3-months)
  • Once 3-year deadline has passed, consider paying the issue fee at the last possible moment to maximize (B) delay.
Maximizing PTA: Avoiding Pitfalls

• File Appeals – if grounds exist and record supports
  – Establish necessary record early in prosecution to support appeal

  – If examiner re-opens prosecution through an office action currently no C-Delay accrues
    • no favorable decision by the Board
    • A-Delay from the Appeal Brief filing until examiner issues an office action to re-open prosecution (any time over 4 months)
    • But New Rule results in B-Delay, if available

  – Currently, some extensions of time during the appeal process do not count against the applicant for PTA
    • But New Rule makes an extension for filing an Appeal Brief applicant delay
Calculate Your Own PTA

- PTA as calculated by USPTO is issued no later than issue date.

- Check USPTO’s calculation of PTA to ensure that it is correct.
  - Based on data found in “PAIR” - but not always accurate.

- Final PTA will be indicated on the face of the issued patent.
Contesting the Office’s PTA Determination

• 37 C.F.R. § 1.705(b): A request for reconsideration no longer must be filed before the payment of the issue fee after Technical Amendment to AIA (signed January 14, 2013)
  – USPTO-determined-PTA is now provided “no later than date of issuance” of the patent (See §154(b)((3)(B)(i))

• 37 C.F.R. § 1.705(d): Reconsideration of final PTA must be filed within 2 months of patent issuance. Only for patents granted before Jan. 14, 2013; for patents granted on or after Jan. 14, 2013: 2 months plus five months of extension; so we are talking about patents granted on or after about Nov. 19, 2013, to take advantage of Novartis rule.

• The deadline for patents granted before Jan. 14, 2013, is not extendable.
Contesting the Office’s PTA Determination

- 35 U.S.C § 154(b)(4)(A): Final Determination of PTA by USPTO can be appealed “exclusively” to the U.S. District Court
  - Applicant must have received a Final Determination in order to appeal to the U.S. District Court
  - Appeal must be filed within 180 days of “the date of the Director’s decision on the applicant’s request for reconsideration” (changed from “after grant of patent” by Technical Amendment)
  - AIA changed the venue from D.D.C. to E.D. Va on September 16, 2011
  - Appeal “exclusively” to U.S. District Court added in Technical Amendment to AIA (signed Jan. 14, 2013)
    - Cannot raise issues that could have been raised before.
What Should Corporate Counsel Be Doing?

- Identify pending applications that cover inventions that are expected to retain value at end of patent term.

- Carefully analyze US PTO’s PTA calculation.
  - Make sure correct under current law.
  - Determine if law not being properly applied by US PTO.

- If disagree, must act quickly to preserve rights.
  - After patent issues, request reconsideration in US PTO within 2 months and prepare to file district court case within 180 days of decision on request for reconsideration.
  - Must file request for reconsideration prior to paying issue fee.
Best Practices To Defeat Double Patenting Rejections

• Avoid terminal disclaimers.

• Maintain demarcation in chain of divisionals to keep §121 “safe harbor”
  – Boehringer Ingelheim Int’l GmbH v. Barr Laboratories, Inc., 592 F.3d 1340 (Fed. Cir. 2010)

• Rejection generally must be based on what previously claimed, not what previously disclosed
  – Eli Lilly v Teva Parenteral Medicines, Inc., 689 F.3d 1368 (Fed. Cir.), reh’g denied (Nov. 2012)
Double Patenting In Litigation

• What if you are the alleged infringer and you are sued for infringement?
  • You argue obviousness-type double patenting, but lose on summary judgment.

• File petition for ex parte reexamination in the PTO where there is no presumption of validity, a lower standard of proof, and broadest reasonable claim construction?

  • USPTO and courts do not have to come to same conclusion. See In re Baxter Int’l, Inc., 678 F.3d 1357 (Fed. Cir. 2012); Fresenius USA, Inc. v. Baxter Int’l., Inc., (Fresenius II), 721 F.3d 1330 (Fed. Cir. 2013), cert denied. (U.S. May 19, 2014)

Thank You!

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