OSHALiANG
Intellectual Property Law

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# 美国专利局对可专利性的解释

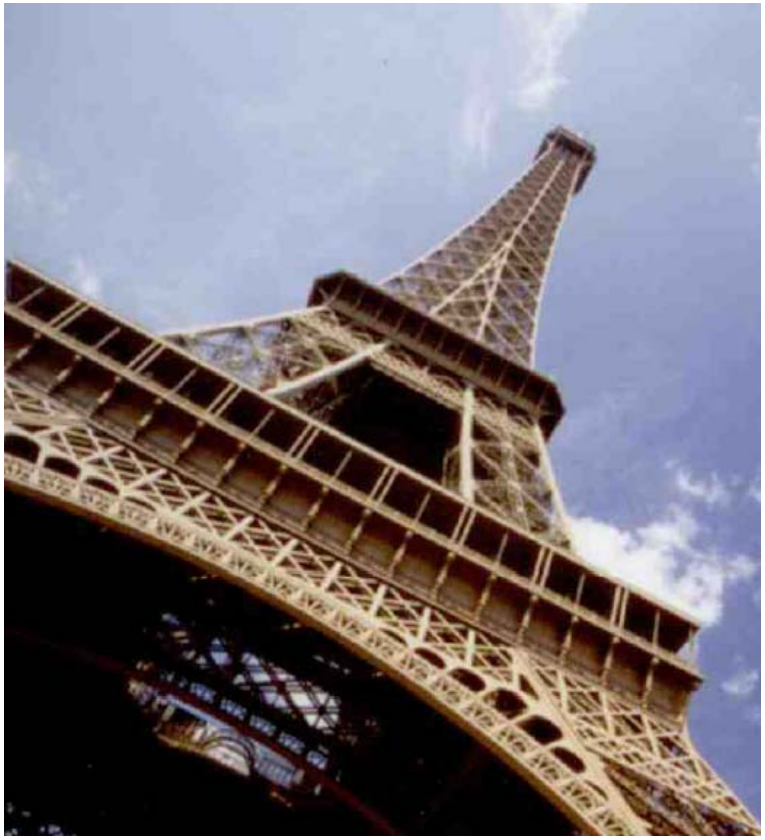
美国欧夏梁律师事务所

梁子樵　　律师

# Office Locations

- Houston, Texas
  - Established 1998
  - Total staff: 95
  - Firm headquarters for admin functions

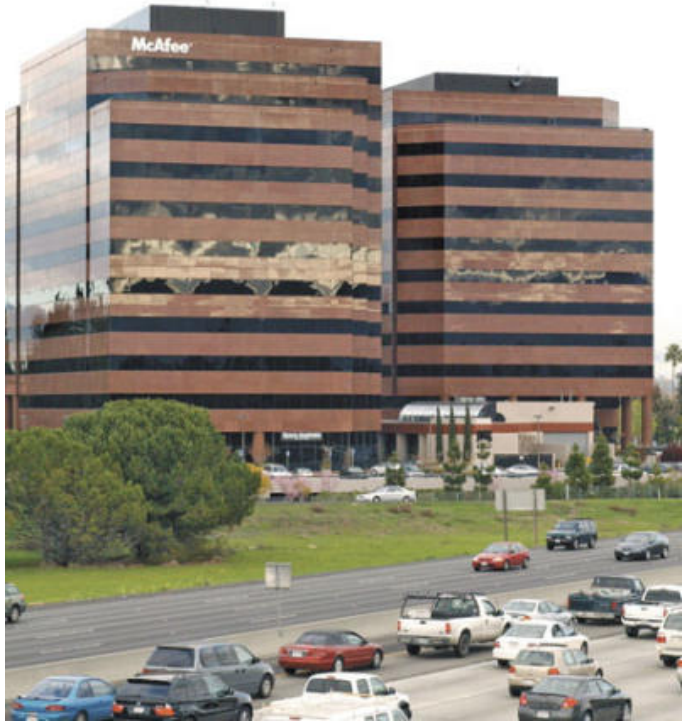
# Office Locations



- Paris, France
  - Established 2001
  - Total staff: 10
  - European and French patent attorneys

# Office Locations

- Santa Clara, CA
  - Silicon Valley
  - Established 2004
  - Total staff: 8
- Software and Electrical Engineering



# Office Locations

- Austin, Texas
  - Established 2007
- Copyright
- Litigation

# Office Locations

- Tokyo, Japan
  - Kasumigaseki
  - Established 2008
- U.S. and EP client liaison
- Licensed to advise Japanese clients on U.S. law

# Office Locations

- Hangzhou, China
  - Established 2013
- Liaison office

# Office Locations

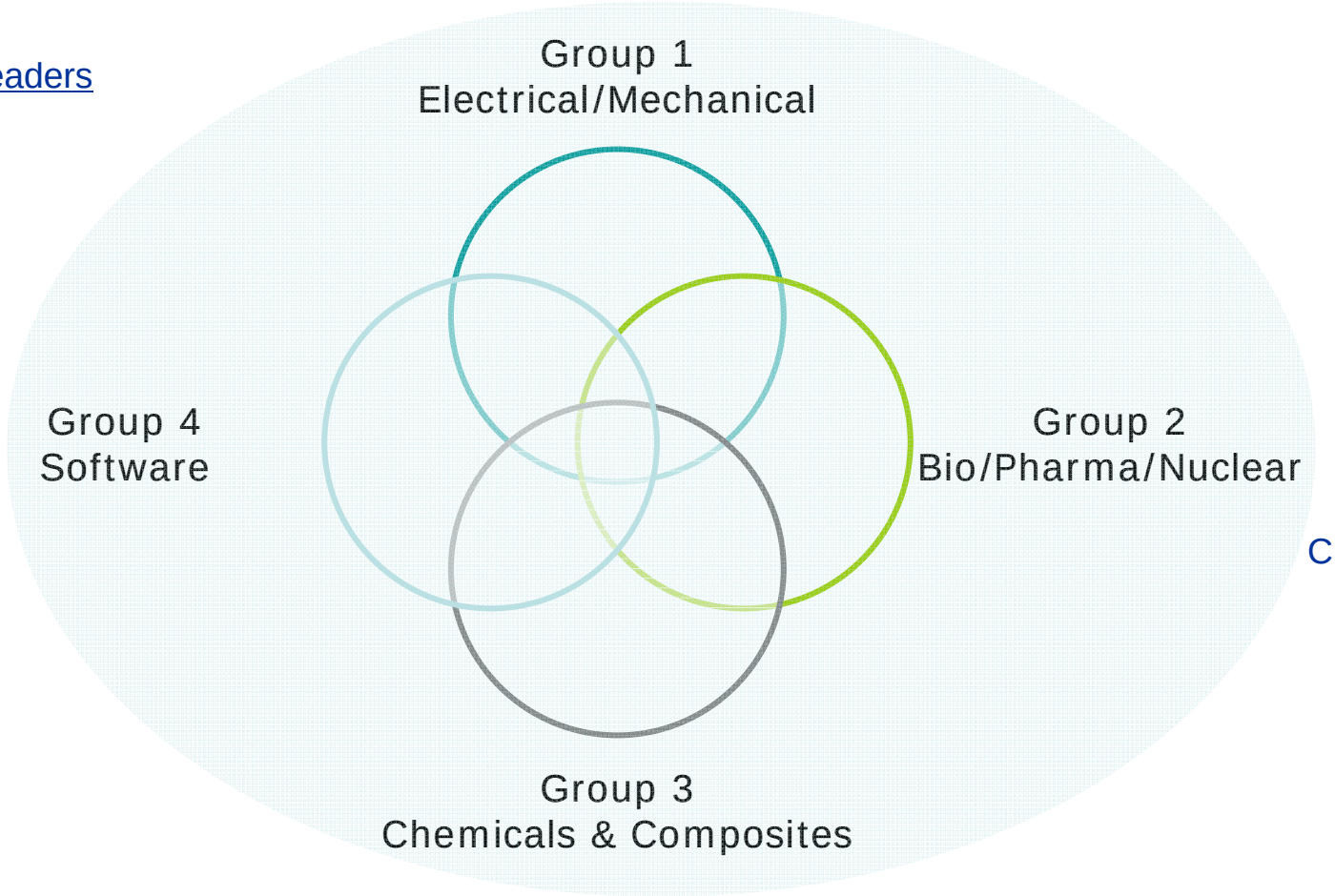
- Washington, D.C.
  - Established 2014
- Litigation office

# Legal Technology Groups

Managing Partner: John Osha

Thomas Scherer

Group Leaders




Robert Lord

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# 梁子樵 简介

- 台湾大学 - 药学系学士
- 美国布朗大学 - 化学博士
- 德州大学医学院（休斯敦） - 教授
- 休斯敦大学 - 法学博士
- 美国：律师，专利代理人
- 台湾：专利师
- **CLP™ （certified licensing professional)**

➢ 业务领域涵盖：专利申请和诉讼，知识产权法律咨询，知识产权资产管理，许可，法律意见与自由运作分析。

# 讲课提纲

美国专利局“可专利的主体”新审查指南

# 中国专利法

**第二条** 本法所称的发明创造是指发明、实用新型和外观设计。

- 发明，是指对产品、方法或者其改进所提出的新的技术方案。
- 实用新型，是指对产品的形状、构造或者其结合所提出的适于实用的新的技术方案
- 外观设计，是指对产品的形状、图案或者其结合以及色彩与形状、图案的结合所作出 的富有美感并适于工业应用的新设计。

**第五条** 对违反法律、社会公德或者妨害公共利益的发明创造，不授予专利权。

- 对违反法律、行政法规的规定获取或者利用遗传资源，并依赖该遗传资源完成的发明创造，不授予专利权。

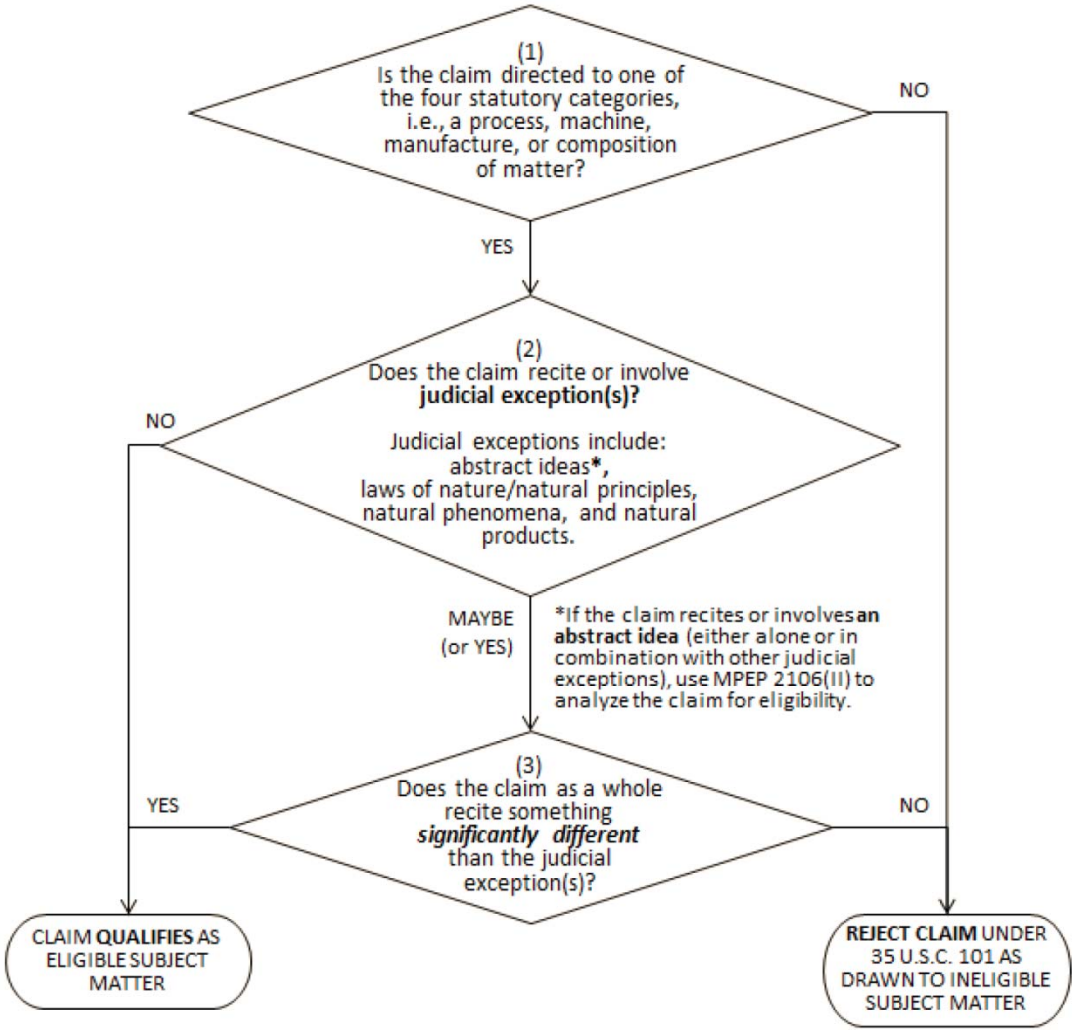
**第二十五条** 对下列各项，不授予专利权：

- （一）科学发现；
- （二）智力活动的规则和方法；
- （三）疾病的诊断和治疗方法；
- （四）动物和植物品种；
- （五）用原子核变换方法获得的物质；
- （六）对平面印刷品的图案、色彩或者二者的结合作出的主要起标识作用的设计。

# Patentable Subject Matter Examination Guideline
# 可专利的标的审查指南

- Guidelines issued by the USPTO on **March 4, 2014**
- Relates to law of nature, natural phenomenon, or natural products
- Myriad Genetics (isolated oligonucleotide non-eligible)
- Mayo v. Prometheus (assay methods, law of nature)
- This impacts all types of claims (machine, manufacture, composition, and process).

# 判断流程


(1)
Is the claim directed to one of the four statutory categories, i.e., a process, machine, manufacture, or composition of matter?
NO
YES
(2)
Does the claim recite or involve **judicial exception(s)?**
Judicial exceptions include: abstract ideas*, laws of nature/natural principles, natural phenomena, and natural products.
NO
MAYBE (or YES)
*If the claim recites or involves **an abstract idea** (either alone or in combination with other judicial exceptions), use MPEP 2106(II) to analyze the claim for eligibility.
(3)
Does the claim as a whole recite something ***significantly different*** than the judicial exception(s)?
YES
NO
CLAIM **QUALIFIES** AS ELIGIBLE SUBJECT MATTER
**REJECT CLAIM** UNDER 35 U.S.C. 101 AS DRAWN TO INELIGIBLE SUBJECT MATTER

# Significantly Different
# 显著的差异

- (1) the claim includes elements or steps in addition to the judicial exception that practically apply the judicial exception in a significant way, e.g., **by adding significantly more to the judicial exception**; and/or
- (2) the claim includes features or steps that demonstrate that the claimed subject matter is **markedly different from what exists in nature** (and thus not a judicial exception).

# Example
# 例子

**A. Composition/Manufacture Claim Reciting A Natural Product**

•Claim 1: A stable energy-generating plasmid, which provides a hydrocarbon degradative pathway.

•Claim 2: A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

# Example
# 例子

**B. Composition vs. Method Claims, Each Reciting A Natural Product**

•Claim 1. Purified amazonic acid.

•Claim 2. Purified 5-methyl amazonic acid.

•Claim 3. A method of treating colon cancer, comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for a period of time from 10 days to 20 days, wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid.

# Example
# 例子

**C. Manufacture Claim Reciting Natural Products**

•Claim: A fountain-style firework comprising: (a) a sparking composition, (b) calcium chloride, (c) gunpowder, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder, and (e) a plastic ignition fuse having one end extending into the second compartment and the other end extending out of the cardboard body.

# Example
# 例子

**D. Composition Claim Reciting Multiple Natural Products**

•Claim: An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.

# Example
# 例子

**E. Composition vs. Method Claims, Each Reciting Two Natural Products**

•Claim 1. A pair of primers, the first primer having the sequence of SEQ ID NO: 1 and the second primer having the sequence of SEQ ID NO: 2.

# Example
# 例子

- Claim 2. A method of amplifying a target DNA sequence comprising:
  - providing a reaction mixture comprising a double-stranded target DNA, the pair of primers of claim 1 wherein the first primer is complementary to a sequence on the first strand of the target DNA and the second primer is complementary to a sequence on the second strand of the target DNA, Taq polymerase, and a plurality of free nucleotides comprising adenine, thymine, cytosine and guanine;
  - heating the reaction mixture to a first predetermined temperature for a first predetermined time to separate the strands of the target DNA from each other;
  - cooling the reaction mixture to a second predetermined temperature for a second predetermined time under conditions to allow the first and second primers to hybridize with their complementary sequences on the first and second strands of the target DNA, and to allow the Taq polymerase to extend the primers; and
  - repeating steps (b) and (c) at least 20 times.

# Example
# 例子

**F. Process Claim Involving A Natural Principle And Reciting Natural Products**

Claim: A method for determining whether a human patient has degenerative disease X, comprising:

•obtaining a blood sample from a human patient;

•determining whether misfolded protein ABC is present in the blood sample, wherein said determining is performed by contacting the blood sample with antibody XYZ and detecting whether binding occurs between misfolded protein ABC and antibody XYZ using flow cytometry, wherein antibody XYZ binds to an epitope that is present on misfolded protein ABC but not on normal protein ABC; and

•diagnosing the patient as having degenerative disease X if misfolded protein ABC was determined to be present in the blood sample.

# Example
# 例子

**G. Process Claims Involving A Natural Principle**

•Claim 1. A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising: exposing the patient to sunlight, wherein the exposure to sunlight alters the neuronal activity in the patient's brain and mitigates the mood disorder.

•Claim 2. A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising: exposing the patient to a synthetic source of white light, wherein the exposure to white light alters the neuronal activity in the patient's brain and mitigates the mood disorder.

# Example
# 例子

**G. Process Claims Involving A Natural Principle**

•Claim 3. A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising:

- providing a light source that emits white light;
- filtering the ultra-violet (UV) rays from the white light; and
- positioning the patient adjacent to the light source at a distance between 30-60 cm for a predetermined period ranging from 30-60 minutes to expose photosensitive regions of the patient's brain to the filtered white light, wherein the exposure to the filtered white light alters the neuronal activity in the patient's brain and mitigates the mood disorder.

# Example
# 例子

**H. Process Claim Reciting An Abstract Idea And A Natural Product**

•Claim: A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises comparing the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence, wherein a difference between the suspected mutant and the wild-type sequences identifies a mutant BRCA2 nucleotide sequence.

•M.P.E.P. 2106（II）

# 讲课提纲

## 化学药品 – 创造性

# Patent Term Adjustment (PTA)

**Background**

•Prior to June 8, 1995, the patent term was 17 years from the date of issuance.

•To comply with GATT, the patent term was changed to 20 years from the filing or priority date for applications filed on or after June 8, 1995.

•USPTO backlog ➔ Delayed granting ➔ Shorter patent terms

•Amendments to 35 U.S.C. 154 by the 1999 American Inventors Protection Act (AIPA) – Patent Term Guarantee

# American Inventors Protection Act (AIPA)

- Amendments to 35 U.S.C. 154 by the 1999 American Inventors Protection Act (AIPA) –Guarantees that a patent would have a term of at least 17 years.
- 35 U.S.C. 154(b)(1):
  - "A Delay" (14-4-4-4 Delay),
  - "B delay" (over 3 years), and
  - "C delay" (delay due to interference, secrecy order, and appeal).

# Patent Term Adjustment (PTA)

- Different Interpretations of 35 U.S.C. 154(b) between the USPTO and applicants resulted in several cases and clarification from the Congress
  - *Wyeth et al. v. Dudas* (January 2010, A & B delay overlaps)
  - Technical Correction to AIA (January 2013; national phase app)
  - *Novartis v. Lee* (January 15, 2014, RCE exclusion)
  - *Mohsenzadeh v. Lee* (March 27, 2014, Divisional Application)

# *Wyeth et al. v. Dudas*

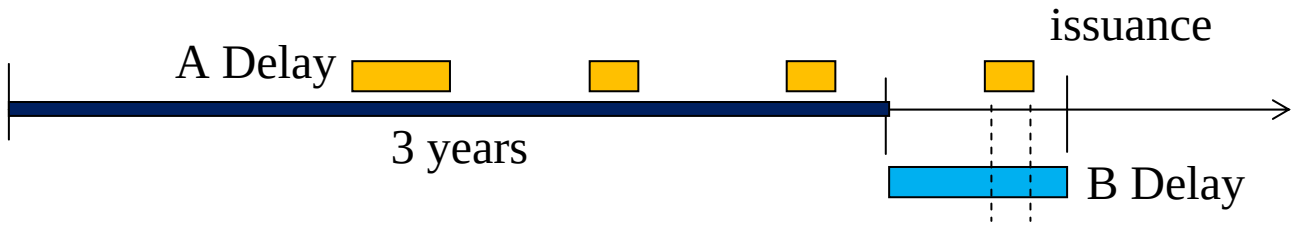
**35 U.S.C. 154(b)(2) LIMITATIONS**

•(A) IN GENERAL –To the extent that periods of delay attributable to grounds specified in paragraph (1) **overlap**, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

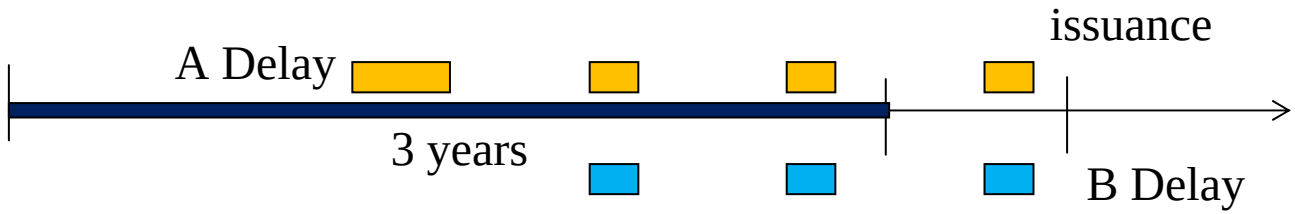
•USPTO published revised Rules on April 22, 2004 (effective May 24, 2004): the entire "B delay" period is relevant for "overlap" consideration during the entire pendency, not just the period after three years.

# *Wyeth et al. v. Dudas*

- Wyeth et al. argue: overlaps occur only when they occur on the same calendar days and B delays do not occur until after 3 years.




USPTO interpretation

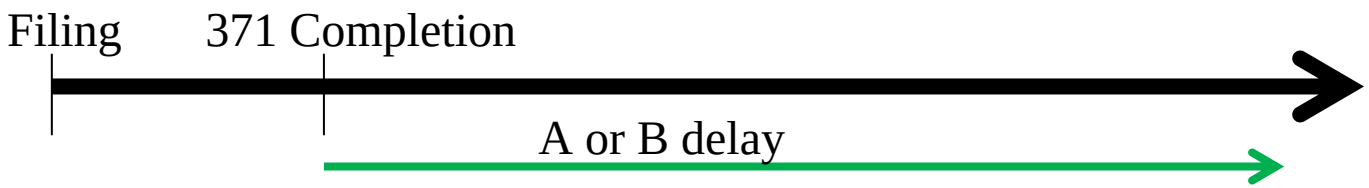



➔ **the PTA is the longer of the "A delay" or the "B delay."**

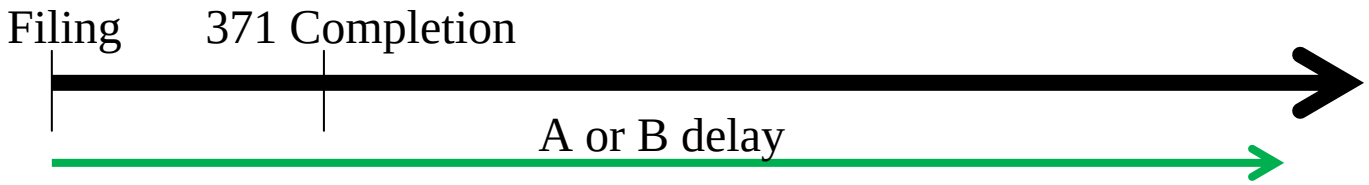
# *Wyeth et al. v. Dudas*

- In a Summary Judgment, DC District Court overturned the USPTO's interpretation of 35 USC 154(b)(2)(A) - ***Wyeth v. Dudas***, 580 F.Supp.2d 138 (D.D.C. September 30, 2008)
- USPTO appealed the decision. (November 28, 2008)
- Federal Circuit unanimously affirmed the DC District Court. - ***Wyeth v. Kappos***, 591 F. 3d 1364, 93 USPQ2d 1257 (Fed. Cir. 2010)

# Technical Corrections to AIA (Jan. 2013)




- For PCT national stage applications, the national stage commencement date (not the 371 requirement completion date) starts the “A delay” and “B delay” clock.



# Patent Term Adjustment

**35 U.S.C. 154(b) ADJUSTMENT OF PATENT TERM.—**

(1) PATENT TERM GUARANTEES.—

(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.— **(14 – 4 – 4 – 4 Adjustment)**

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.— **(over 3 years Adjustment)**

# Patent Term Adjustment

**35 U.S.C. 154(b)(1)(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.**—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

•(i) provide at least one of the notifications under **section 132** or a notice of allowance under **section 151** not later than **14 months** after—

- (I) the date on which an application was filed under **section 111(a)** ; or
- (II) the **date of commencement** of the national stage under **section 371** in an international application;

•(ii) respond to a reply under **section 132** , or to an appeal taken under **section 134** , within **4 months** after the date on which the reply was filed or the appeal was taken;

•(iii) act on an application within **4 months** after the date of a decision by the Patent Trial and Appeal Board under **section 134** or **135** or a decision by a Federal court under **section 141** , **145** , or **146** in a case in which allowable claims remain in the application; or

•(iv) issue a patent within **4 months** after the date on which the issue fee was paid under **section 151** and all outstanding requirements were satisfied,

# Patent Term Adjustment

**35 U.S.C. 154(b)(1)(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY**.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under **section 111(a)** in the United States or, in the case of an international application, **the date of commencement** of the national stage under **section 371** in the international application ***not including*** –

(i)any time consumed by continued examination of the application requested by the applicant under **section 132(b** );

(ii)any time consumed by a proceeding under **section 135(a)** , any time consumed by the imposition of an order under **section 181** , or any time consumed by appellate review by the Patent Trial and Appeal Board or by a Federal court; or

(iii)any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C),

# *Changes to Implement the Patent Law Treaty*
## 78 FR 62368 (Oct. 21, 2013)

- 37 CFR 1.704(c)(12): Effective December 18, 2013, failing to provide an application in "**condition for examination**" within **eight months** from the filing or national stage commencement date constitutes applicant delay.
- 37 CFR 1.704(f) – defines “condition for examination”

# 37 CFR 1.704(f)

An application filed under 35 U.S.C. 111(a) is in condition for examination when the application includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has

- papers in compliance with § 1.52,
- drawings (if any) in compliance with § 1.84,
- any English translation required by § 1.52(d) or § 1.57(a),
- a sequence listing in compliance with § 1.821 through § 1.825 (if applicable),
- the inventor's **oath or declaration** or an application data sheet containing the information specified in § 1.63(b),
- the basic filing fee (§ 1.16(a) or § 1.16(c)),
- the search fee (§ 1.16(k) or § 1.16(m)),
- the examination fee (§ 1.16(o) or § 1.16(q)),
- any **certified copy of the previously filed application** required by § 1.57(a), and
- any application size fee required by the Office under § 1.16(s).

# 37 CFR 1.704(f)

An international application is in condition for examination when the application has entered the national stage as defined in § 1.491(b), and

•includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has

•papers in compliance with § 1.52,

•drawings (if any) in compliance with § 1.84,

•a sequence listing in compliance with § 1.821 through § 1.825 (if applicable),

•the inventor's **oath or declaration** or an application data sheet containing the information specified in § 1.63(b),

•the search fee (§ 1.492(b)),

•the examination fee (§ 1.492(c)), and

•any application size fee required by the Office under § 1.492(j).

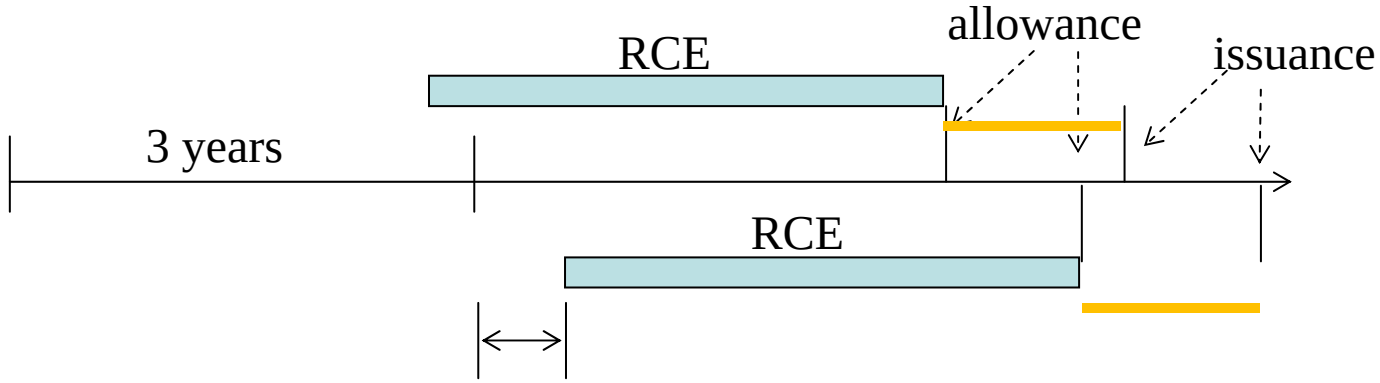
# Patent Term Adjustment

**35 U.S.C. 154(b)(1)(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY**.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under **section 111(a)** in the United States or, in the case of an international application, the date of commencement of the national stage under **section 371** in the international application not including—

- (i) any **time consumed by continued examination** of the application requested by the applicant under **section 132(b )**;

# *Novartis AG v. Lee*
## 2013-1160 (Fed. Cir. 2014)

- USPTO position: any filing of RCE tolls the B Delay.
- Novartis Argument: Statute excludes only the "time consumed by the continued ***examination***."



# *Novartis AG v. Lee*
## (Fed. Cir. Jan. 15, 2014)

- (i) the application was pending at least three years; and
- (ii) an RCE was filed (whether the RCE was filed before or after three years does not matter).

- Under the current version of 37 CFR 1.705, the deadline to seek PTA reconsideration in the USPTO is **two months from the issue date**, extendable by an additional **five months** pursuant to Rule 1.136(a).
- Under the current version of 35 USC 154(b)(4)(A), the deadline to file a civil action is within **180 days** after the date of the Director's decision on the applicant's request for reconsideration.

# *Mohsenzadeh v. Lee*
## (E.D. Va., March 27, 2014)

- US District Court for the Eastern District of Virginia **upheld** the USPTO's long-standing position that PTA accrued in a parent application does not carry over to a continuing application (at issue here, a divisional)
- A continuing application is still entitled to its own PTA based on events occurring during its own examination.

# MPEP (version 9)

USPTO released Edition 9 of MPEP on March 28, 2014, which includes a substantially revised Chapter 2700 on Patent Terms and Extensions.

http://www.uspto.gov/web/offices/pac/mpep/index.html

# Summary

- PTA = A delay + B delay – Overlap
- Overlap of A and B delays occurs only on the same calendar date
- For PCT national phase applications, both A delay and B delay starts from the commencement of national stage, subjecting to the condition of completing the filing requirements in 8 months from commencement.
- RCE filing tolls the patent term adjustment only during the examination period.
- Divisional Application??

# Chemical Compounds – Inventiveness

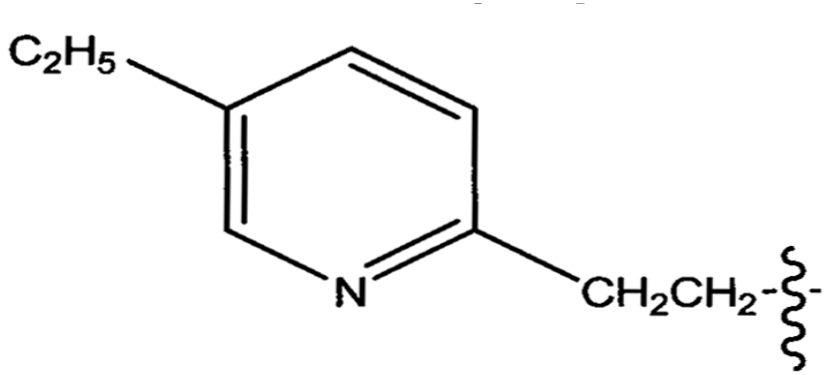
# Obviousness of Chemical Compounds

- **A known compound may suggest compounds with similar structure because such compounds often have similar properties and, therefore, chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.**

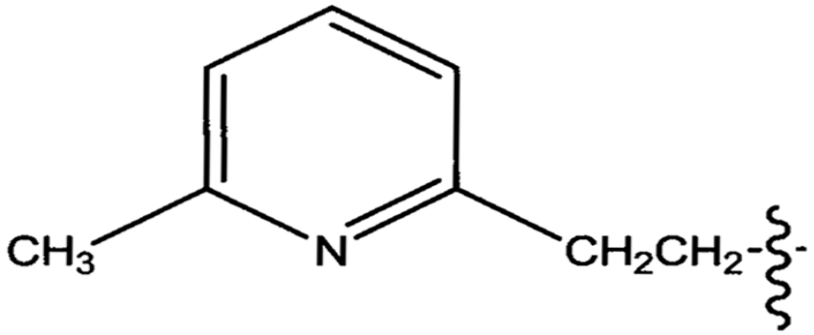
- **However, in order to make a prima facie case of unpatentability in such instances, a showing that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention is also required.**

# *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*

**492 F.3d 1350 (Fed. Cir. 2007)**



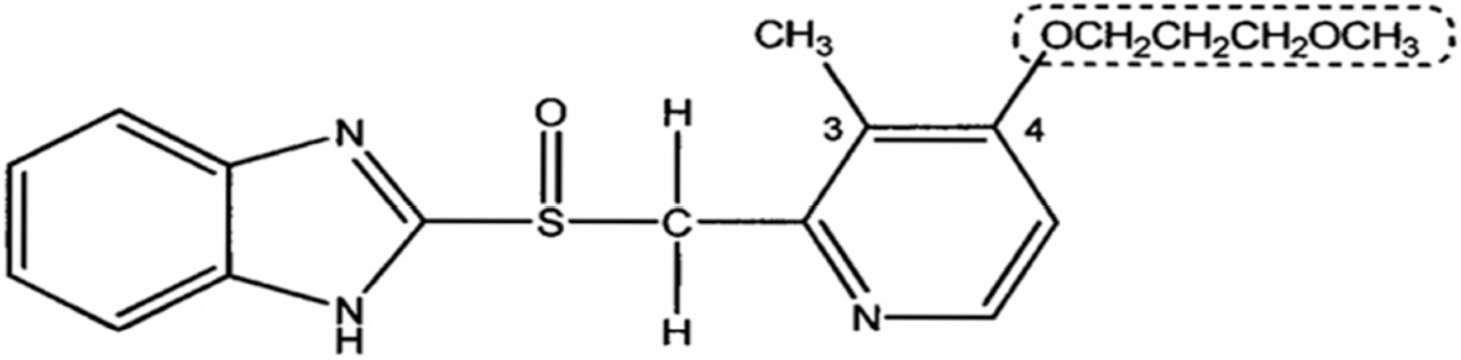

Pioglitazone



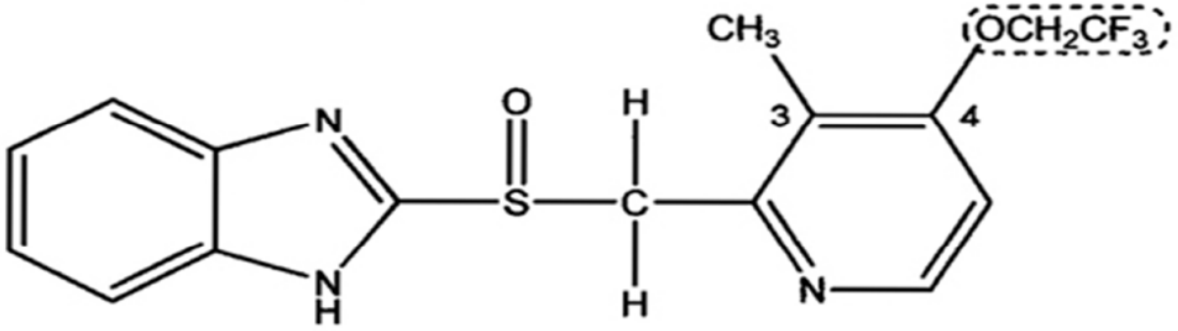

compound b

# *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*

**533 F.3d 1354 (Fed. Cir. 2008)**




Rabeprazole




Lansoprazole

## *Otsuka Pharmaceutical Co. v. Sandoz, Inc.*,
**678 F.3d 1280 (Fed. Cir. 2012)**

- First, the court determines whether a chemist of ordinary skill would have selected the asserted prior art compounds as lead compounds, or starting points, for further development efforts . . . .
- The second inquiry in the analysis is whether the prior art would have supplied one of ordinary skill in the art with a reason or motivation to modify a lead compound to make the claimed compound with a reasonable expectation of success

# 谢谢！