The Impact of Recent Changes in US Patent Laws on Patent Management and Value Creation in Research Scientist and Institution

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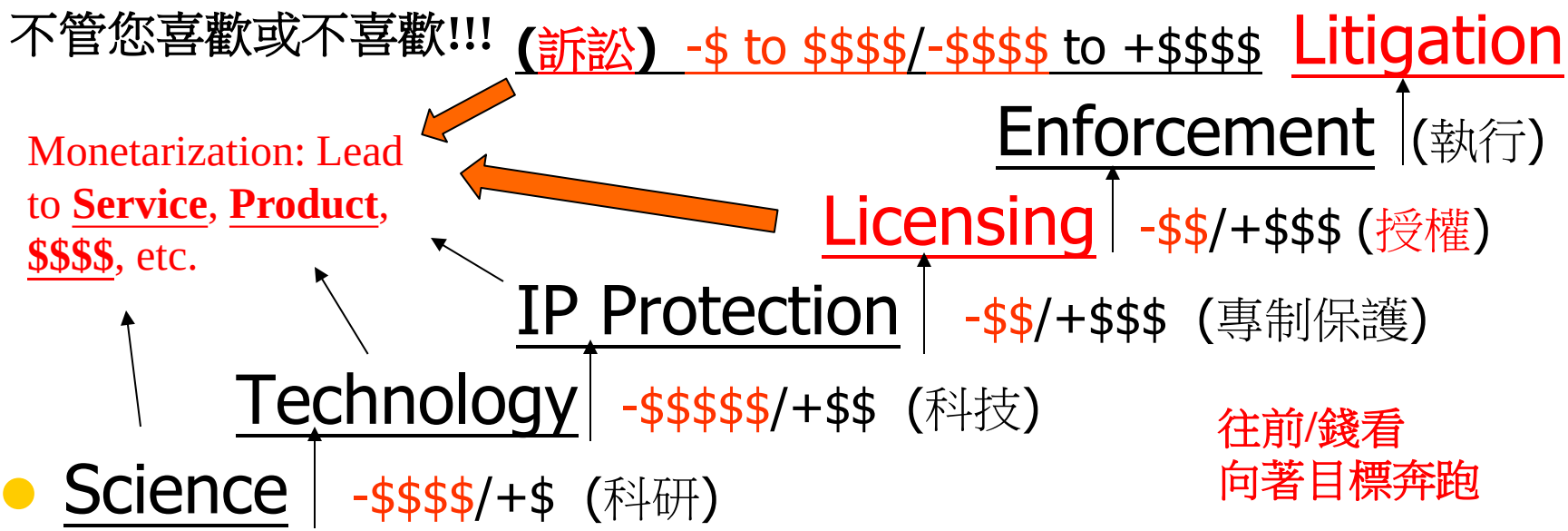
Presentation Objective 拋磚引玉

Disclaimer:

- I am not a lawyer. This lecture is a presentation from a scientist to a scientist and is not an legal/IPR opinion. I am a business consultant consulting on your business which can be affected by the laws. For legal advise, please seek assistance from your legal counsel. [set the stage for IP lawyers]
- As a scientist [or Research Institution] heavily involved in R&D and protecting of the knowledge/technology/invention in the biggest market in the world (US), you should aware of all the rules affecting your invention and business operation.
  [科研者 → 懂法律、法規、智財/知權 與 商業 的科研者]

Tech Commercialization: The Role of Scientist/Institution

Entry Barrier is Getting Higher and Higher (A Road of No Return 不歸路)



- Nowadays, if you not suing someone or being sued by others and win, you are not a player (ur a sitting duck)
  假如不不是被人家告或是去告人家 你根本不是玩家
- Know-how: management, financing, legal, M&S, etc.

The Role of Scientist/Institution

Entry Barrier is Getting Higher and Higher (A Road of No Return 不歸路)

- **A Good start is half of the success** - The more you know and the more you can do it yourself, the better for your patent lawyer be able to work with you and easier for your potential customers/licensees/co-developers to license your protected technology

- **Business-driven R&D** – build a protected tech portfolio
- **Smart patent practice** – high quality high value creation (from R&D → patent filing, prosecution [strategy, maximum market coverage, retain rights, delay cost, buy time (PCT + >1 filing country for early opinion)…]
- **Business-driven licensing/negotiation → service/product or agreement, enforcement/litigation…**
- **Business-driven patent management** – identify valuable research, avoid AIA/PTAB post-grant challenge and infringement litigation, skillfully enforcement on own patent rights, seek early partner to share costs, etc.

Changes, Changes, Changes…

Turmoil and Transformation in the U.S. Patent System – Impact on Global Biotech/Pharm Scientists and Business Developers

- The world is keep on changing, but some principles remain unchanged - They just interpret differently…
- Examples: AIA (2011), Bilski v Kappos (2010), Mayo v Prometheus (2012), AMP v Myriad (2013), Alice v CLS Bank (2014), [Philip v AWH (2005), Natulius v Biosig (2014)] and more…
- Issues: AIA, subject matter eligibility, claim construction, interpretation, indefiniteness, abusive practice… 商場如海、善習泳者勝、明規矩者贏

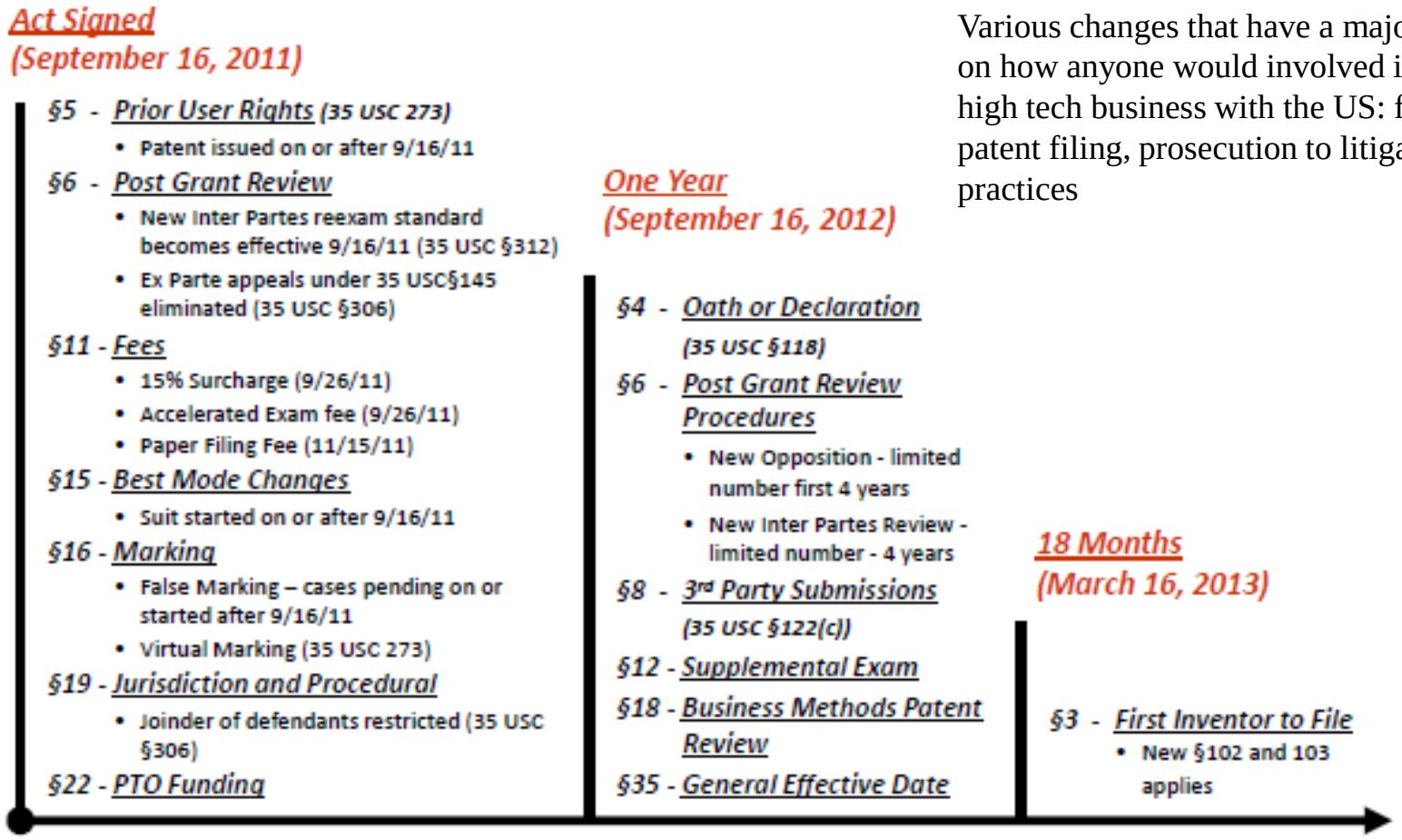
"Everything Old is New Again": Turmoil and Transformation in U.S. Patent Litigation

(http://www.independentinventorsofamerica.org/wp-content/uploads/2015/02/Investment-Grade-Asset_V2-1-1.pdf)

- 2014-15 may be remembered as the year the USPTO/PTAB, Supreme Court and Congress wiped out billions of dollars in booked IP value:
  - ✓ In 2015, the gross value of patent sales is down 83%...
  - ✓ The number of patents sold is down about 50%, and
  - ✓ The average price per patent is down about 55%...
  - ✓ Harder to patent monetarization; but better opportunity for good science/tech/high quality patent…
- University/Institution as a NPE, how to increase revenue?
  - ✓ Carnegie Mellon University v Marvell Technology (US$1.54B in compensatory damages)
    [3-9-2009, CMU sue Marvell Technology for infringing two CMU patented innovative chip technology that significantly improves the ability to accurately detect data stored on hard disk drives. On 12-26-2012, after a four-week trial, a jury in Federal District Court in Pittsburgh found that Marvell had willfully infringed both of CMU's patents and unanimously awarded the university a royalty for past infringement of $1.169 billion. Post-trial, the District Court found Marvell's infringement willful, awarded an additional $287 million in enhanced damages + post-judgment interest + royalties, raising the total judgment to $1.535 billion. Marvell is on appeals, Case No. 2:09-CV-00290-NBF, Appeal No. 14-1492. The appeal is fully briefed and awaiting oral argument. 1-2015]

Various Effective Dates of AIA

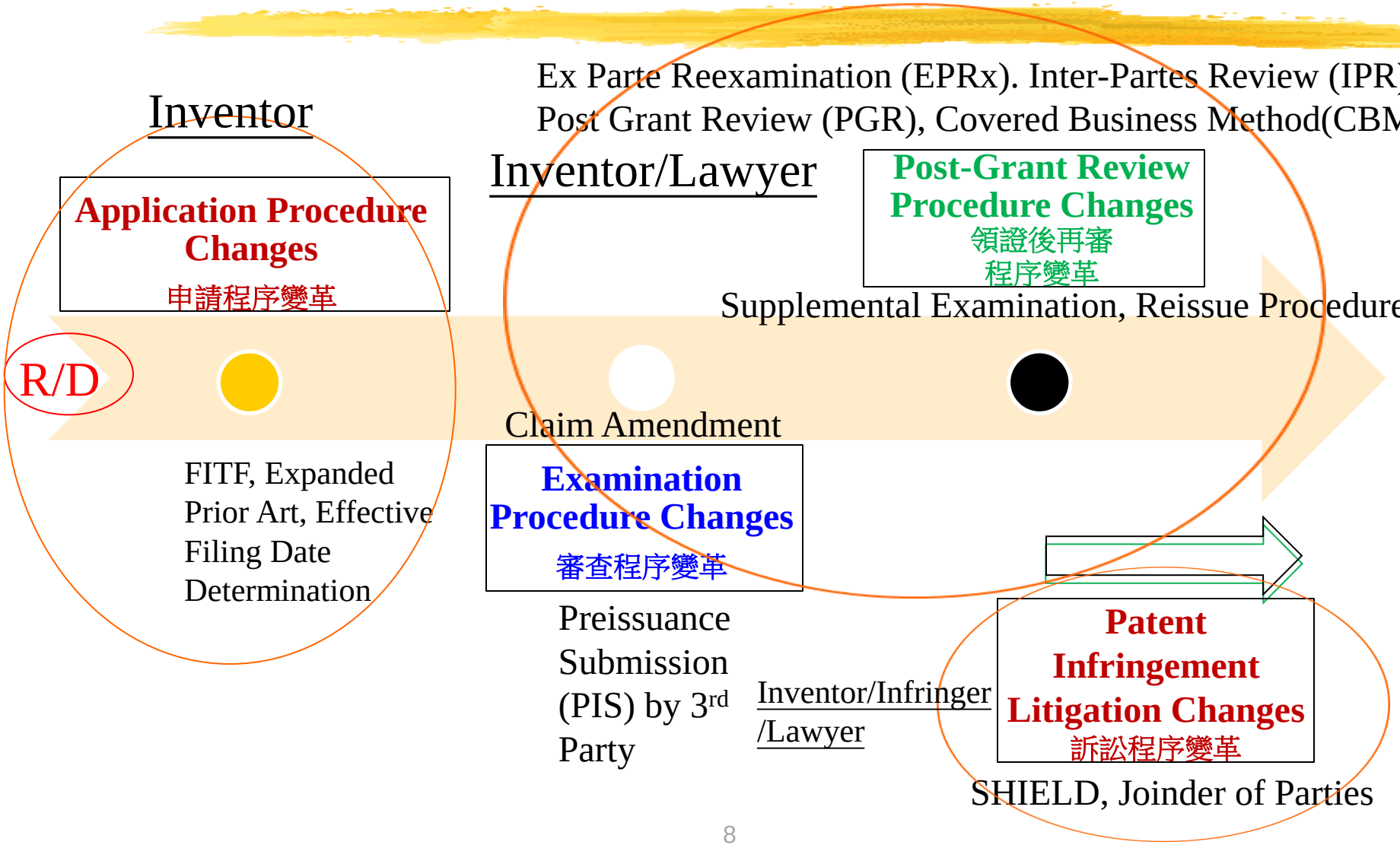
Effective Date: Immediately, 12 Months and 18 Months Later



Various changes that have a major effect on how anyone would involved in doing high tech business with the US: from patent filing, prosecution to litigation practices

The World After AIA (9/16/2011 → 3/16/2013 → Beyond)

Idea/Tech/R&D → IP (Creation/Protection/Management/Utilization)



Legal Requirements for Utility Patent

United States Code/Title 35/Chapter 10/Section XXX

- Statutory Subject Matter (35 USC 101) 法定容許事物
- **Utility (35 USC 101)** 實用性
- **Novelty (35 USC 102)** 新穎性
- **Non-obviousness (35 USC 103)** 非顯而易見 創造性
  [第二十二条 授予专利权的发明和实用新型，应当具备新颖性、创造性和实用性]
- Disclosure - Enablement 可使用 and Best Mode 最佳方法 (35 USC 112, *1st* Paragraph in the Specification)
- Inequitable (Illegal) conduct [i.e., inventor, applicant, prior act, transfer of rights,...] (Fraud, Deceptive Intention/Conducts, **35 USC 251**)
- **Litigation** - Claim Construction/Scope/Specification/Intrepreatation, Patent Infringement Literal and Doctrine of Equivalents, Direct and Indirect Infringement

Statutory Subject Matter (35 USC 101)

After Alice v CLS Bank 2014 [Machine-or-Transformation Test Not Enough]

Some Recent Examples: [Diamond v. Diehr, 1981][**Bilski** v. Kappos, 2010][**Alice** v. CLS Bank, 2014] [Abstract Idea]

- **Mayo** v. Prometheus [Supreme Court, argued December 7, 2011, decided March 20, 2012]

  Holding: Claims directed to a diagnostic method that involved observing a natural correlation were not patent eligible subject matter [Mayo Test] [cffDNA, Ariosa v Sequenom, 6-12-2015]

- AMP v. **Myriad** [Supreme Court, Argued April 15, 2013, decided June 13, 2013][Nature Product]

  Holding: Naturally occurring DNA sequences, even when isolated from the body, cannot be patented, but artificially created DNA is patent eligible because it is not naturally occurring

- BB&T v. Maxim filed 9-16-2013 [DDR Holdings, LLC v. Hotels.com, L.P., Appeal No. 2013-1505 (Fed. Cir. Dec. 5, 2014) confirm eligibility Biz Method, software+computer]

  Covered Business Method Petition (CBM) under AIA of 2012

  Maxim patent 5,949,880 (filed in 1996; issued in 1999) claims "transfer of valuable information between a secure module and another module" and sue BB&T of patent infringement; BB&T counter claim: Maxim patent nothing more than an attempt to patent a well-known and un-patentable abstract idea"

USPTO Guidance on Patent Subject Matter Eligibility After May-Myriad-Alice Supreme Decision

- Supreme Court's decisions: **Mayo** Collaborative Services v. Prometheus Laboratories, Inc. (2012), Association for Molecular Pathology v. **Myriad** Genetics, Inc. (2013),
- 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature" (see "USPTO Issues Interim Guidance Regarding Mayo v Prometheus").
- Guidance on the Myriad decision that was issued on June 13, 2013 (see "USPTO Issues Memo on AMP v. Myriad to Examining Corps").
- Guidance For Determining Subject Matter Eligibility Of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products," March 4, 2014 (or "Myriad-Mayo Guidance" as the file is named)
- Supreme Court's recent decision: **Alice** v CLS Bank (2014)
- Memorandum to the patent examining corps with the preliminary examination instructions, June 25, 2014; USPTO 2014 Interim Guidance on Patent Subject Matter Eligibility, issued December 16, 2014 [USPTO Releases New Guidance on Patent Subject Matter Eligibility - On **July 30, 2015**, the USPTO released a set of additional guidance in respond to comments received from the 2014 Interim Guidance (2014 IEG) on December 26, 2014. The Update responds to "six themes" from the over sixty comments received by the USPTO on its previous Guidance on 35 U.S.C. § 101.]

The Types of PTAB Trials

- ***Inter Partes* Review ("IPR"):** Trial proceeding available for all patents except those that are still eligible for PGR.
- **Post Grant Review ("PGR"):** Trial proceeding only available for first inventor to file patents and only during first nine months after patent issues.
- **Covered Business Method Review ("CBM"):** Modified PGR proceeding available where (1) petitioner (or petitioner's privy) has been sued or threatened with a suit; and (2) patent qualifies as a "covered business method" patent.
- **Derivation Proceedings:** Determines the true inventor of an invention.

How To Protect Your Patent Against PTAB "Death Squads“

FM Koenigbauer et al., Venable LLP, 5-21-2014

- **The Patent-Killing Era** - “We have an enterprise (i.e., the USPTO) that has 8,000 employees creating a product (i.e., patents) and has 300 employees destroying the same product in contested proceedings. The question: “How long can this “business model” last?” If a private sector company were engaged in the same behavior they would quickly be out of business.” [CAFC Chief Judge Randall Rader, AIPLA annual meeting, October 2013, call the **PTAB** “**death squads killing property rights**.”]
- **Opposite view** - The purpose of patents is not to create “property rights.” Rather it’s to promote the progress by disseminating information. As a part of that, inventors are supposed to be given a limited amount of exclusivity, but **only on** things that are **new** and **non-obvious** to those skilled in the art, and only such that it creates the **incentive to create** that invention. We should be happy to get rid of them [those bad patents], and not because it’s “killing property rights,” but because they’re getting rid of economic inefficiencies that hold back innovation and progress.

What Is Clear After Two Years of IPR Under AIA

10-21-2014, the National Law Review, Patrick T. Driscoll, et al,

http://www.natlawreview.com/article/inter-partes-review-initial-filings-paramount-importance-what-clear-after-two-years-

- When the patentability of claims challenged is determined on a per petition basis, in 9% of petitions all claims were deemed patentable, in **15% of petitions some claims were deemed unpatentable**, and in **73 % of petitions all of the claims were deemed unpatentable** [as compare to a mere 31% for Inter Partes Reexaminations]. It therefore appears that once the PTAB gets involved, the chances that the challenged claims will be struck down rises precipitously
- 20 percent of the IPR requests are not instituted, which translates into 207 patents escaping the process by not being taken up
- If the PTAB reaches a determination on the patentability of an instituted petition, there is only a 9 percent chance that the patent will escape unscathed; a mere six cases have escaped the PTAB so far

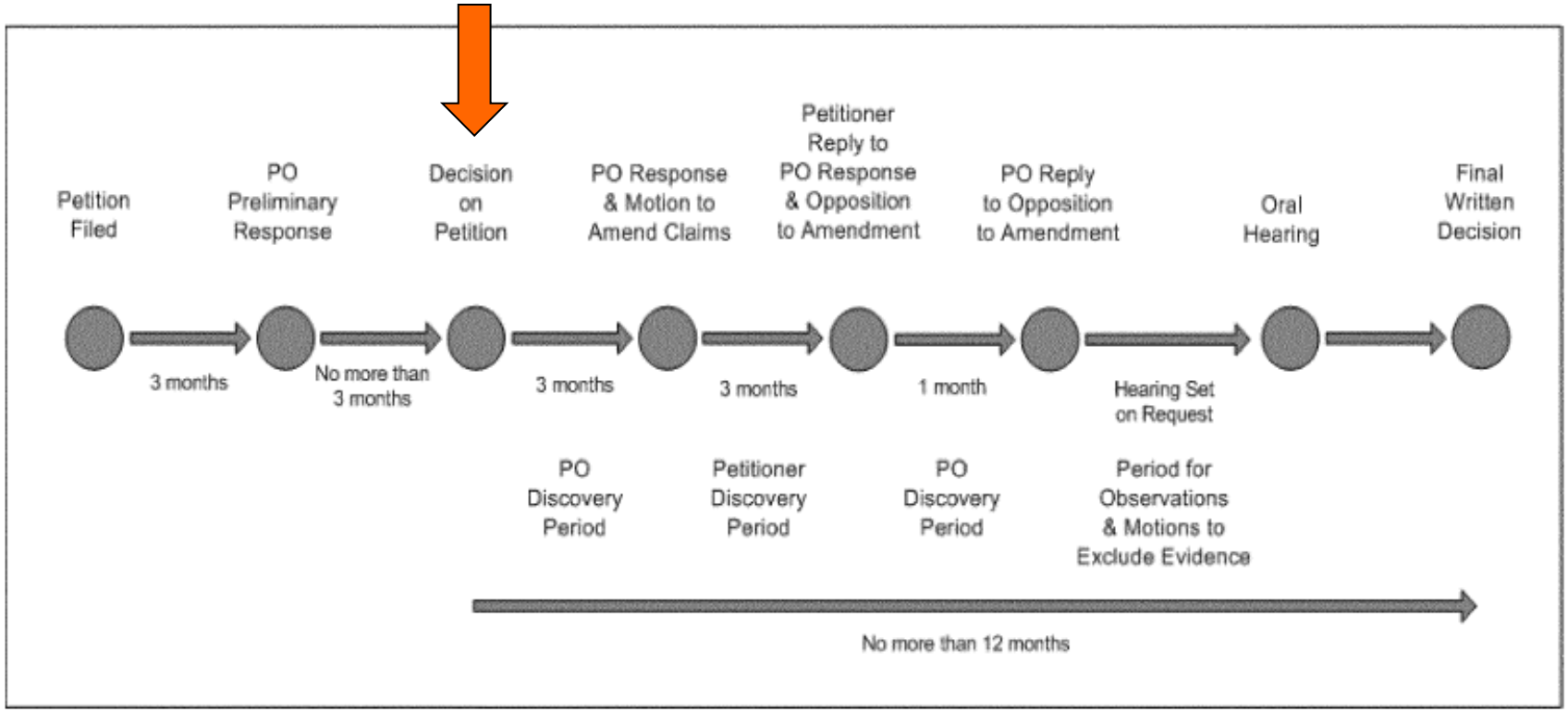
- Therefore, a **petitioner's** best strategy is to ensure that a review is instituted, while a **patent owner's** best defense against an IPR is to make certain that one is not instituted in the first place

How to Survive the Patent Killing Era:

IP Management Process – Increase Source/Revenue and Decrease Cost/Expenses 開源與節流

- IP Management draws on 4 basis core competencies and experience
  - ✓ Patent source identification and patent value determination
  - ✓ Patent prosecution, counseling, and opinion
  - ✓ Licenses, agreement and due diligence
  - ✓ Litigation (market countries of interest), mediation, alternative dispute resolution and arbitration
- Defining Strategy – Enhancing the value by proactive management → increasing quality of the total IP portfolio [not a single patent any more]
- Defining Value (can take many forms, either tangible or intangible) – cash flow, market exclusivity vs cross-licensing, participating in joint R/D projects, services or contracts, etc.

PTAB Trial Timeline (IPRs and CBMs)



How to Survive the Patent Killing Era:

Four Basic Processes - Increase Source/Revenue and Decrease Cost/Expenses 開源與節流

- Process 1: Identify valuable R/D results and create new value [Proactively training/mentoring, early DD, gap funding, strategize technology development, integrate IP activities with new R/D strategy, market-driven IP filing, strong IP right supported by quality prosecution, etc.]
- Process 2: Maximizing existing IP value [Align IP portfolio with business and tech objectives, value-driven acquisition and maintenance cost control, coordinating international prosecution and litigation activities, etc.]
- Process 3: Assessing potential IP value and risks [Due diligence to determine costs/risks and benefits, reduce vulnerability by investigating designing around and patent around, cross-licensing, strategic IP portfolio development, etc.]
- Process 4: Realizing value [Through IP enforcement, through business arrangements such as licensing, acquisitions, financings, collaborative arrangement, avoid commodity markets, etc.]

Conclusions 開源與節流

- Survival and kill - strongest patent - avoid being killed during the early process, wait for the opportunity and make a kill 三年唔發市、發市要當三年
- Smart patenting/filing and effective IP management requires
  - ✓ IP expertise [learn as you can] [更主動、更精準、更有效的管理/應用]
  - ✓ More focused and rigorous ways to realize value [Due Diligence]
- Effective IP management requires everyone to know
  - ✓ The technology, the business, the industry and the IP function
- Work together as a multidisciplinary team [團隊合作] - contribute individually and work together to form a formidable team
- Effective IP management is critical to Tech Commercialization [business] success in the 21 century

Anti-Troll and Anti-Stupid Patents

Headline News - Examples

- September 2014 - Supreme Court Sends Stupid Software Patent Back To Federal Circuit, Again [right after SCOTUS decision on Alice v CLS]
- August 2014 - Electronic Frontier Foundation (EFF) to Patent Office: End the Flood of Stupid Software Patents
- June 2015 - In Another Post-Alice Brief, EFF Urges Federal Circuit to Apply Law
- October 2012 - The Federal Circuit to Take on Software Patents ... Again
- June 2014 - Bad Day for Bad Patents: Supreme Court Unanimously Strikes Down Abstract Software Patent
- And More… [spill-over effect to many other patents…]

U.S. Judicial System – Patents

U.S. Supreme Court

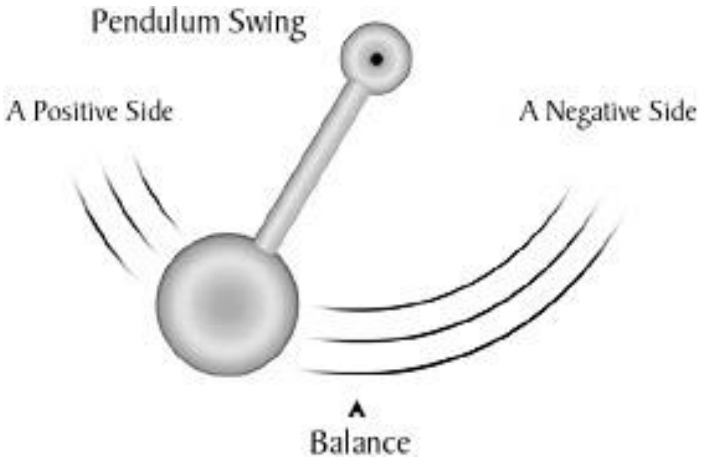
Federal Circuit

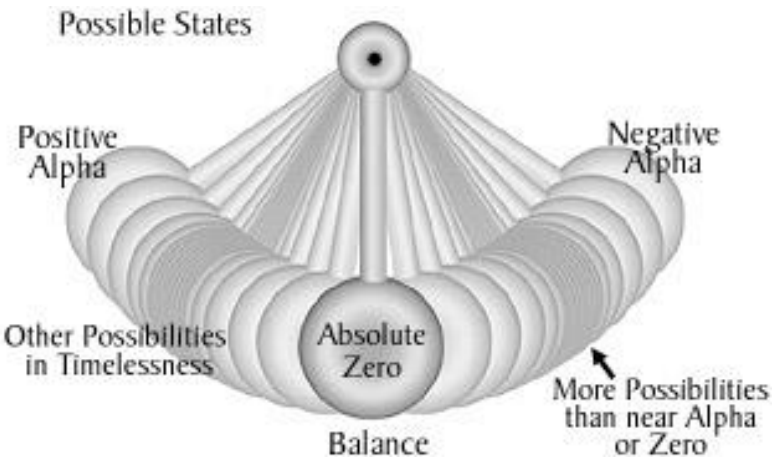
Quasi-Judicial Federal Agencies

- **International Trade Commission**
- **Patent Trial Appeal Board**

- **94 Federal District Courts (at least one in each state)**
- **U.S. Court of Federal Claims**

Balance and Pendulum





Background – Leahy-Smith America Invests Act (AIA) of 2011

- Most significant patent reform legislation since Patent Act of 1952
- Enacted September 16, 2011 (59 years later)
- Introduces various changes to US patent law that will have a major effect on how anyone involved doing high tech business with the US and involved with US patent filing, prosecution and/or litigation practices

Impact of AIA - Summary

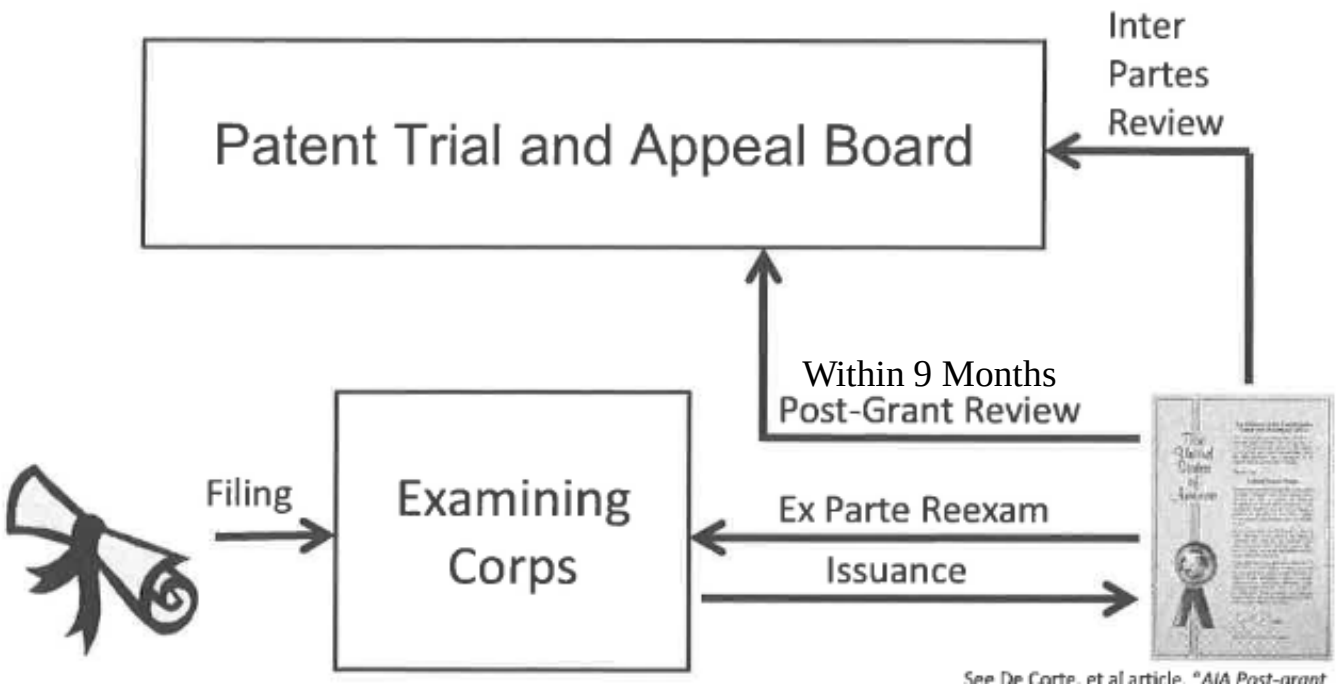
- **R&D/Application Procedure Changes 申請程序變革**
  - ✓ 專利申請 (filing) 的動作必須加快, 發明揭露政策 (disclosure policy) 的改變, 檢索政策 (search policy) 的改變, 善用臨時專利申請 (Provisional Application), 善用各種專利申請管道(國際專利合作條約、專利法條約等)
- **Examination Procedure Changes 審查程序變革; Post-Grant Review Procedure Changes 領證後再審程序變革**
  - ✓ 在「審查程序變革」與「領證後再審程序變革」，建議可以善用多方複審(IPR)與核准後複審(PGR)程序，有效對付競爭者(competitors)及非專利實施實體(NPE)，善用Supplemental examination, Reissue procedure,...
- **Patent Infringement Litigation Changes 訴訟程序變革**
  - ✓ 在「訴訟程序變革」上，建議產業的專利管理人應有所認知，尤其新法案於訴訟程序改變會造成非專利實施實體(NPE)訴訟成本增加，可降低企業受NPE的困擾

PTAB (Patent Trial and Appeal Board)

- SUMMARY: The Leahy-Smith America Invents Act (AIA) establishes several new trial proceedings to be conducted by the Patent Trial and Appeal Board (Board) including **inter partes review, post-grant review, the transitional program for covered business method patents, and derivation proceedings**. In separate rulemakings, the USPTO is revising the rules of practice to implement these provisions of the AIA that provide for the trial proceedings before the Board. The Office publishes in this notice a practice guide for the trial final rules to advise the public on the general framework of the regulations, including the structure and times for taking action in each of the new proceedings. [Effective Date: commencing on or after September 16, 2012, as well as derivation proceedings commencing on or after March 16, 2013]
- FOR FURTHER INFORMATION CONTACT: Michael Tierney, Lead Administrative Patent Judge, Board of Patent Appeals and Interferences (BPAI, will be renamed as Patent Trial and Appeal Board PTAB on September 16, 2012)

PTAB Procedures

After 9 Months Post Granted or 9 Months after Termination of PGR whichever Later



See De Corte, et al article, "AIA Post-grant

PTAB - PGR v IPR

程序	核准後複審 (Post-Grant Review，PGR)	多方複審 (Inter Partes Review，IPR)
訴願提起人	除專利權人外之任何人均可提出。 皆需揭露是否為真正利害關係人。	
標的	任何具有至少一專利申請範圍，其有效申請日在2013年3月16日之後之有效專利。	任何有效專利（不包含可提起PGR程序之專利）
使用時機	專利核准後9個月內	專利核准或PGR程序終止後9個月後（以較晚的為主）
理由	35 U.S.C. §101,102,103,112	35 U.S.C. §102,103

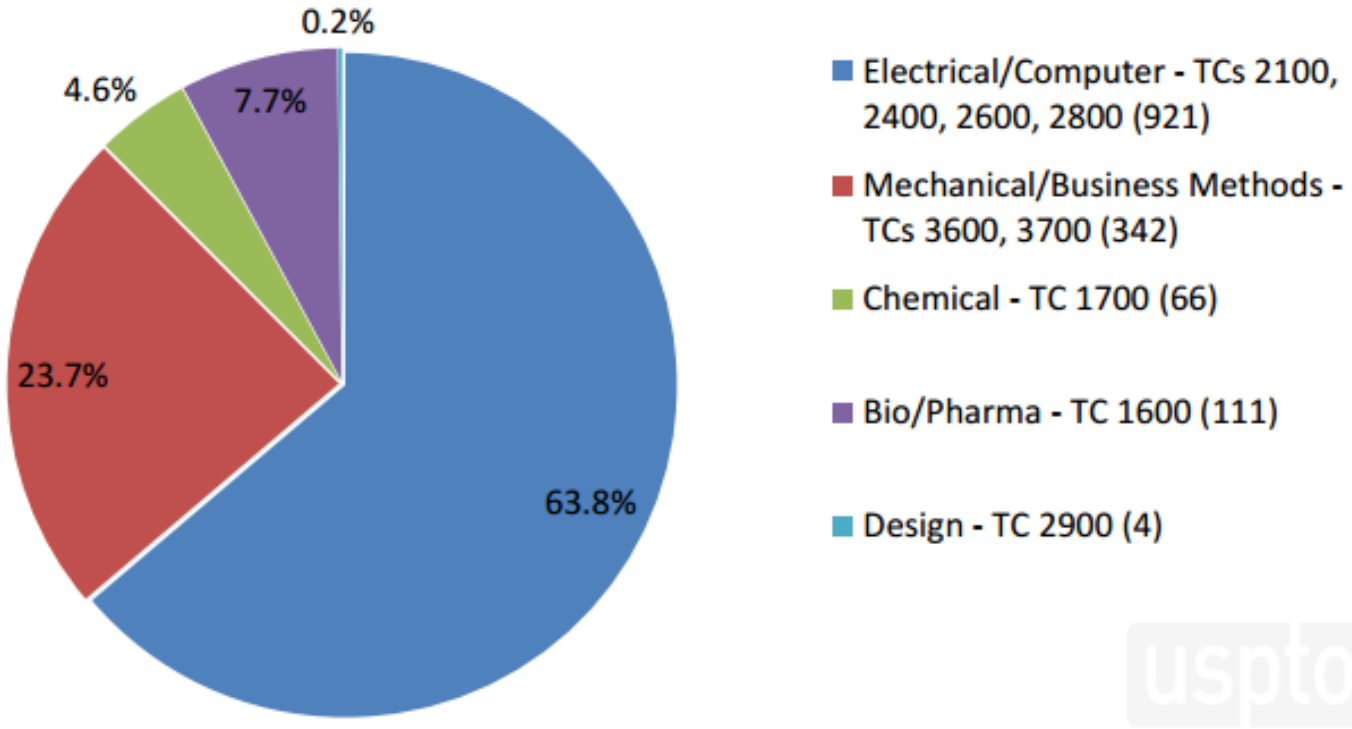
程序	核准後複審 (Post-Grant Review，PGR)	多方複審 (Inter Partes Review，IPR)
門檻	“more likely than not that at least 1 of the claims challenged in the petition unpatentable” (標準較高)	“resonable likelyhood that the patitioner would prevail” (標準較低)
上訴	訴願提起人及專利權人均可上訴至聯邦巡迴上訴法院(CAFC)	
審理時間	受理後12個月內（可以延長6個月）	

What Is a PTAB Trial?

- The America Invents Act of 2011 ("AIA") created four new administrative trial proceedings that took effect on September 16, 2012
- Trials are evidentiary proceedings that are adjudicated primarily on the written record
- Proceedings replace *inter partes* reexamination and "interferences"
- Trials require written advocacy skills, the eye of a trial lawyer, and appellate skills

What Type of Technology Is Being Challenged?
[Broad-Based, Wide-Spread]

Source: USPTO (last visited July 15, 2015) (available at http://www.uspto.gov/sites/default/files/documents/062515_aia_stat_graph.pdf)



IPR Petition Dispositions (as of June 25, 2015)

Source: USPTO (last visited July 15, 2015) (available at http://www.uspto.gov/sites/default/files/documents/062515_aia_stat_graph.pdf).

		Trials Instituted	Joinders	Percent Instituted	Denials	Total No. of Decisions on Institution
IPR	FY13	167	10+	87%	26	203
	FY14	557	15+	75%	193	765
	FY15 *	583	102+	71%	281	966
CBM	FY13	14	0	82%	3	17
	FY14	91	1+	75%	30	122
	FY15 *	67	2+	71%	28	97
PGR	FY15 *	2	-	100%	-	2
DER	FY14	0	0	0%	3	3

IPR Final Dispositions (as of June 25, 2015)

Source: USPTO (last visited July 15, 2015) (available at http://www.uspto.gov/sites/default/files/documents/062515_aia_stat_graph.pdf).

		Settlements	Adverse Judgments	Final Written Decisions
IPR	FY13	38	2	0
	FY14	210	39	130
	FY15 *	351	58	278
CBM	FY13	3	0	1
	FY14	27	3	13
	FY15 *	39	3	37
PGR	FY15 *	2	-	-

IPR Success Rates (through 4/30/2015)

Source: USPTO (last visited July 15, 2015) (available at http://www.uspto.gov/sites/default/files/documents/inter_partes_review_petitions_%2004%2030%202015_0.pdf))