The Impact of AIA and Alice on IP Management: Effects on Global Biotech/Pharma R&D

創新、創技、創智、創富

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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 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. [Laws only protect those who understand laws (and have enough money to hire those lawyers, very good lawyers)]

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, double patenting...
- 商場如海、善習泳者勝、明規矩者贏

Everything Old is New Again...

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

- On one hand AIA Relationship to Global Practices
 (http://www.uspto.gov/patent/laws-and-regulations/america-invents-act-aia/global-impacts-aia#heading-2)
 - ✓ Help the U.S. <u>align with international norms</u>, which provides a renewed opportunity to <u>harmonize the international patent system</u> and <u>facilitate</u> <u>office cooperation through work-sharing</u> with international patent offices.
 - Top down alignment of applicable law harmonization coupled with the bottom up convergence at the practice and administrative level work-sharing enables offices to increasingly work together to provide a higher quality examination, more predictability in prosecution process, and cost reduction for applicants for examinations around the world.
 - ✓ We can no longer afford to ignore new economic realities and the enabling role that the patent system plays. The U.S. has acted by enacting the first 21st Century patent system. The time is now for <u>widespread international</u> agreement and commitment to <u>making the global patent system simpler</u>, <u>more certain</u>, <u>and user-friendly for all innovators</u>.

Everything Old is New Again... 陣痛期

Turmoil and Transformation in U.S. Patent System

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

- On the other hand According to the US Inventor and Independent Inventors of America [Hostile Environment for Inventors Harms the Economy], 2014-2015 may be remembered as the year the USPTO/PTAB, U.S. 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%...
- New laws have created alternate ways to invalidate issued patents
- The Supreme Court has thrown the definition of what can be patented into chaos
- New patent suits have dropped by as much as 40% in one year. [Most of that drop is in software, a very important American industry. All of this is happening in the U.S. while other countries, like China, strengthen their own patent systems to grow their economies.
- More U.S. companies are going out of business than are starting up [first time in American history] [killing the very engine that made the US the greatest economic power in history]

IP/Patent and Patent Protection

Fundamental Principle: Balance Between Rewarding Innovation versus Monopoly [Scope, Boundary, Definition, Interpretation, ...]

A patent is a "territorial protection" granted by a sovereign state for a limited period of time to exclude others to practice (making, using, selling, importing) your invention in that State, in return the inventor must disclose the invention for the public good [屬地性有限期排他權]

[IP Protection starts with <u>patent filed 可回溯性</u>; can only enforced after issuance but can commercialize before issuance to save source/time]

Dispute Area

書地為王 先佔先贏 放狗為虐 非請勿進 合縱連橫 坐地分肥

Patent Boundary And Uncertainty 專利範圍及不確定性。 Patent Landscape

Patent Minefield

Territorial, Time, Patentability, Claims

Invalid, Not Infringed

Neglected Area

專利,就是科技競爭力 廖和信,天下遠見出版社,2003

Your Own Patent Freedom-to-Opera

Your Own Patent

Freedom-to-Operate

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)
- Pay patent fee
- <u>Litigation</u> Claim Construction, interpretation, Indefiniteness, Patent Infringement Literal and Doctrine of Equivalents, Direct and Indirect Infringement

Various Effective Dates of AIA

Effective Date: Immediately, 12 Months and 18 Months Later

Act Signed (September 16, 2011)

- §5 Prior User Rights (35 USC 273)
 - Patent issued on or after 9/16/11
- §6 Post Grant Review
 - New Inter Partes reexam standard becomes effective 9/16/11 (35 USC §312)
 - Ex Parte appeals under 35 USC§145 eliminated (35 USC §306)

§11 - Fees

- 15% Surcharge (9/26/11)
- Accelerated Exam fee (9/26/11)
- Paper Filing Fee (11/15/11)

§15 - Best Mode Changes

Suit started on or after 9/16/11

§16 - Marking

- False Marking cases pending on or started after 9/16/11
- Virtual Marking (35 USC 273)

§19 - Jurisdiction and Procedural

- Joinder of defendants restricted (35 USC §306)
- §22 PTO Funding

One Year (September 16, 2012)

§4 - Oath or Declaration

§6 - Post Grant Review Procedures

- New Opposition limited number first 4 years
- New Inter Partes Review limited number - 4 years
- §8 3rd Party Submissions (35 USC §122(c))
- §12 Supplemental Exam
- §18 <u>Business Methods Patent</u> <u>Review</u>
- §35 General Effective Date

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

> <u>18 Months</u> (March 16, 2013)

§3 - First Inventor to File

New §102 and 103 applies

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

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

Inventor

Application Procedure Changes

申請程序變革

FITF, Expanded Prior Art, Effective Filing Date **Determination**

Ex Parte Reexamination (EPRx). Inter-Partes Review (IPR), Post Grant Review (PGR), Covered Business Method(CBM)

Inventor/Lawyer

Post-Grant Review Procedure Changes 領證後再審 程序變革

Supplemental Examination, Reissue Procedure

Claim Amendment

Examination **Procedure Changes**

審查程序變革

Preissuance **Submission** (PIS) by 3rd **Party**

Inventor/Infring er/Lawyer

Patent Infringement Litigation Changes

SHIELD, Joinder of Parties

AIA Take Home Messages:

R&D, Application Procedure Changes

- Issues: FITF, EFD, Disclosure, Prior Art, Inventor Grace Period, etc.
 - Establish FITF and EFD as early as possible, strategic disclosure to block others, understand what is and what is not prior art, beware of problematic disclosure by collaborative partners with common ownership and joint research agreement
- Implications: More preparation work (extensive prior art search and analysis, better filing strategy, better disclosure/enablement in provisional filing, etc.)[more expensive]; need to establish internal policy on prior art searching and patent landscape monitoring, identify competitor's technology and patents early on; policy on how to deal with collaborative partners; strategic disclosure, race with time to file, etc.

AIA Take Home Messages:

Pre-Issuance Submission, Post Grant Proceedings

- Challenge competitor's patent using prior art before the patent is issued [Pre-issuance submission (PIS) by 3rd party]
- Challenge competitor's patent using post grant proceedings:
 - ✓ Derivation procedure [EFD, novelty, obviousness], Post grant review (PGR), Inter partes review (IPR), Extra partes reexamination (EPRx), Business method opposition (CMB), Supplemental examination and reissue procedure
- Strengthen your own patent
 - Claim amendment, supplemental examination and reissue procedure
- Implications: Better science/tech/patent, internal policy to monitoring patent landscape, challenge competitor's patent, but be prepared to face the challenge from your competitors, challenge and strengthen your own patent

Patent Subject Matter Eligibility

- Statutory Subject Matter (101)
- Utility (101)
- Novelty (Prior art)(102)
- Non-obviousness (102/103)
- Enablement/Best mode (112)

Section 101 - Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Flowchart for Subject Matter Eligibility

DETERMINE WHAT APPLICANT HAS INVENTED AND IS SEEKING TO PATENT

- Identify and understand any utility and/or practical application asserted for the invention.
- Review the detailed disclosure and specific embodiments of the invention
- Review the claims

CONDUCT A THOROUGH SEARCH OF THE PRIOR ART

DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH THE SUBJECT MATTER ELIGIBILITY REQUIREMENT OF 35 U.S.C. §101

- Does the claimed invention fall within an enumerated statutory category?
- Does the claimed invention fall within a §101 judicial exception (law of nature, natural phenomena, or abstract idea)?
 - Does the claimed invention cover a §101 Judicial exception, or a practical application of a §101 judicial exception
 - Practical application by physical transformation?
 - Practical application that produces a useful (35 USC 101 utility), tangible, concrete result?
 - Does the claimed invention preempt an abstract idea, law of nature, or natural phenomenon (§101 judicial exception)?
- ¶ Establish on the record a prima facie case

EVALUATE APPLICATION FOR COMPLIANCE WITH 35 U.S.C §112

DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. §§102 & 103

CLEARLY COMMUNICATE FINDINGS, CONCLUSIONS AND THEIR BASES

 Review all the proposed rejections and their bases to confirm any prima facie determination of unpatentability.

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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 <u>diagnostic method</u> that involved observing a <u>natural correlation</u> were not patent eligible subject matter [Mayo Test] [cffDNA, Ariosa v <u>Sequenom</u>, 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 Mayo-Myriad-Alice Supreme Decision

- Supreme Court's decisions: <u>Mayo</u> Collaborative Services v. Prometheus Laboratories, Inc. (2012), Association for Molecular Pathology v. <u>Myriad</u> 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: <u>Alice</u> v CLS Bank (2014)
- Memorandum to the patent examining corps with the preliminary examination instructions, June 25, 2014; <u>USPTO 2014 Interim Guidance on Patent Subject Matter Eligibility</u>, <u>issued December 16</u>, <u>2014 [USPTO Releases New Guidance on Patent Subject Matter Eligibility On <u>July 30</u>, <u>2015</u>, 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.]</u>

What Is a USPTO/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

PTAB (Patent Trial and Appeal Board)

Your are Running Against Time - for Patent Owner (PO)

Patent Review Processing System (PRPS) - PRPS is the PTAB's e-filing and case management system. A link to PRPS, relevant notices, a Quick Start Guide, technical notes, and PRPS-related FAQs are located here.

Trial Proceeding Timeline



Filing a Petition

Strategy Decisions: The Petition

Timing and Joinder

Prior Art/Other Challenges

Claims

Claim Construction

The Preliminary Response

What Happens After Institution of Trial?

Objections to Evidence; Initial Conference Call with the PTAB;

Discovery; Deposition(s); Patent Owner Response;

Motion to Amend; Motion to Exclude;

Trial Hearing;

Final Decision

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 9 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.

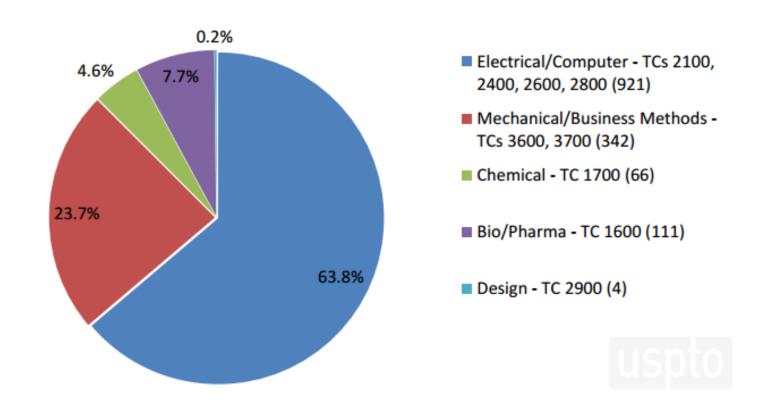
IPR Petition Dispositions (as of June 25, 2015)

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 |
|-----|--------|----------------------|----------|-----------------------|---------|---|
| | FY13 | 167 | 10+ | 87% | 26 | 203 |
| IPR | FY14 | 557 | 15+ | 75% | 193 | 765 |
| | FY15 * | 583 | 102+ | 71% | 281 | 966 |
| | FY13 | 14 | 0 | 82% | 3 | 17 |
| СВМ | FY14 | 91 | 1+ | 75% | 30 | 122 |
| | FY15 * | 67 | 2+ | 71% | 28 | 97 |
| PGR | FY15 * | 2 | - | 100% | - | 2 |
| DER | FY14 | 0 | 0 | 0% | 3 | 3 |

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)



Post-Alice Alice in the PTAB: First 6 Months

Robert Sachs, Survey of Patent Invalidations Since Alice, www.law360.com (Jan. 13, 2015)

| | PTAB Decisions | Patents | Claims |
|--------------------------------------|-------------------|---------|--------|
| Not Invalid | 2 | 2 | 38 |
| Held Invalid or Likely Invalid | 36 | 36 | 286 |

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Post-Alice in the District Courts:

First 6 Months Robert Sachs, Survey of Patent Invalidations Since Alice, www.law360.com (Jan. 13, 2015)

| | District Court Decisions | Patents | Claims |
|--------------|--------------------------|---------|--------|
| Not Invalid | 11 | 20 | 535 |
| Held Invalid | 29 | 56 | 1,488 |

Post-Alice in the Federal Circuit:

First 6 Months Robert Sachs, Survey of Patent Invalidations Since Alice, www.law360.com (Jan. 13, 2015)

| | Fed. Cir. Decisions | Patents | Claims |
|--------------|------------------------|---------|--------|
| Not Invalid | 1 | 1 | 27 |
| Held Invalid | 6 | 12 | 344 |

How To Protect Your Patent Against PTAB "Death Squads"

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

The Patent-Killing Era

CAFC Chief Judge Randall Rader, AIPLA annual meeting, October 2013, call the PTAB "death squads killing property rights."

Opposite View

- ✓ <u>Inventors are given a patent only on</u> 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 <u>happy to get rid of</u> those <u>bad patents which do not</u> <u>deserve a patent</u>, and not because it's "killing property rights," but because we are getting rid of economic inefficiencies that hold back innovation and progress.

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 [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.]

The Tales of Two IP Utilization Systems - Old v New

- Old System R/D → Tech → IP Application/Prosecution → IP Management → IP Enforcement/Litigation → Utilization/ Monetarization [\$\$\$/Agreement/Service/Product]
- New System (Biz-Driven) Better science/tech, smarter IP identification/application/prosecution, earlier challenge early kill or monetarization (via early quasi-litigation), early licensing, share prosecution/litigation/development cost with partner...
- Old linear system → New biz-driven system move up the timeline of licensing/litigation activities → Consequently better and smarter IP management and commercialization

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

Conclusions 開源與節流

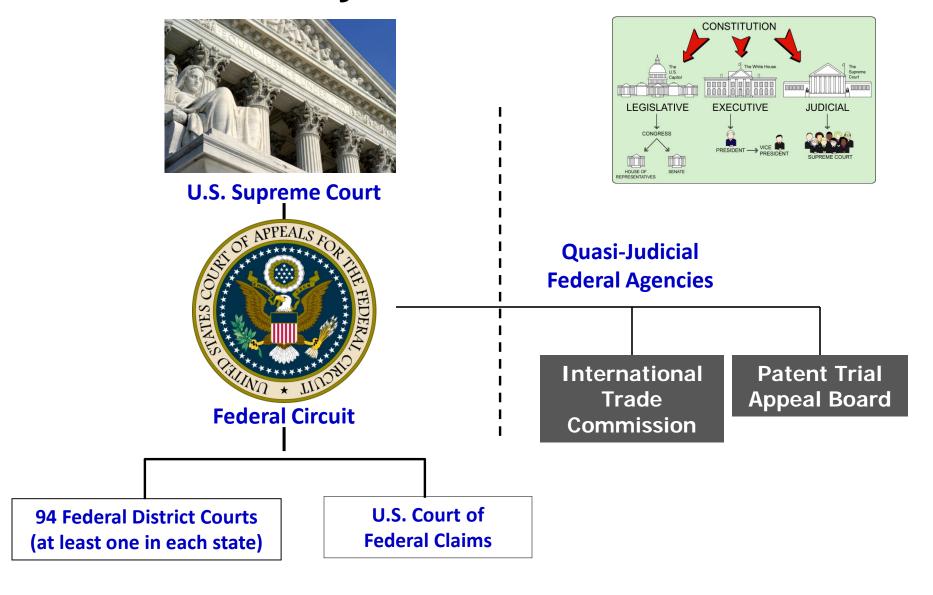
- Better science/tech, better IP protection, filing, prosecution and more effective management, utilization...
- Early survival/kill strongest patent avoid being killed during the early process, wait for the opportunity and make a kill 三年唔發市、發市要當三年
- Smart patenting and effective IP management requires
 - ✓ 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

PTAB and PTAB Troll

The PTAB as a Hedge Fund Tool? Scott A. McKeown, Post-Grant Practice Group, January 15, 2015

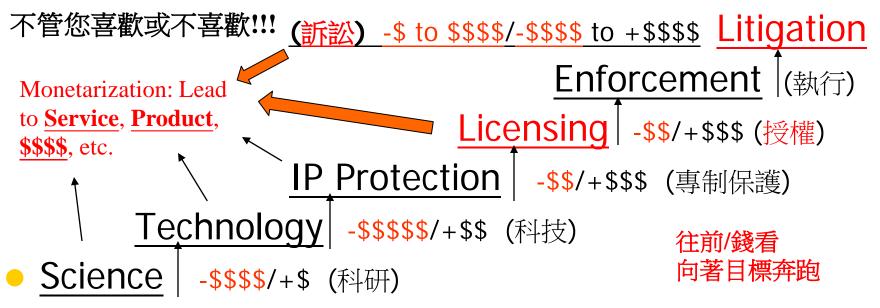
- "PTAB Trolls" manipulate the new administrative trial system of PTAB.
 "PTAB Trolls" attempt to extract settlements from patentees involved in high value litigation disputes
- Other versions PTAB Trolls that will take a "short" position in a stock mere filing of an IPR can spook investors, impacting trading volumes
 enough to cause a temporary, but significant, price drop (i.e., quick profit
 for a short seller) these efforts have mostly failed, but not all.
- Next up, well financed hedge funds taking on key drug patents of the pharmaceutical industry? The founder of Dallas-based Hayman Capital Management, Kyle Bass, announced to the world that he planned to attack 15 drug companies via IPR. "We are going to challenge and invalidate patents through the IPR process ... (and) we are not going to settle . . . The companies that are expanding patents by simply changing the dosage or the way they are packaging something are going to get knee capped. .. This is going to lower drug prices for Medicare and for everyone."

U.S. Judicial System — Patent Dispute Resolutions



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.

IP/Patent and Patent Protection

Fundamental Principle: Balance Between Rewarding Innovation versus Anti-Competition + More [商場如海、善習泳者勝、明規矩者贏]

- Four ways to protect you IP rights (智慧財產/知识产权)
 - ✓ Trade Secret Law 營業秘密法
 - ✓ Copyright Law 著作權法
 - ✓ Patent Law 專利法 Utility, Design, Plant
 - ✓ Trademark Law 商標法
 - [know-how, show-how, documentation, information, IP capital, regulatory, and many others]
- Pharmaceutical world employs all four laws + more to protect their IP [regulatory data and market exclusivity, patent mining, creative patenting, patent restoration and extension, compensation for interference, etc.] (Anti-trust, Anti-competitive, Section 337 ITC investigation, etc.)
- IP Laws vary slightly but significantly among all countries (and you should take advantage on those differences)
- As a player, you must learn how to play the game

How Patent Rights Can Be Lost

專利的喪失 (或專利被判無效、或不可執行、或非法行為)

- Maintenance fees are not paid 没交維持費
- Shown that patent fails to adequately teach how to make and use the invention 專利內容沒有適當教他人如何使用
- Prior art references are uncovered which anticipate the invention or render it obvious 被發現先有已知文獻技術
- Patent owner engages in certain types of *illegal* conduct,
 i.e., commits antitrust or other violations connected with the patent 發明人或權人非法專利有關行為
- Patent applicant committed "fraud on the USPTO" by failing to disclose material information, such as relevant prior-art references, to the USPTO during period when application pending 對專利局有犯法行為



Major Differences between IPR, PGR, and CBM

| Inter Partes Review (IPR) | Petitioner | Estoppel | Standard | Basis |
|----------------------------------|--|---|--|--|
| Post Grant Review (PGR) | Person who is not the patent owner and has not previously filed a civil action challenging the validity of a claim of the patent Must identify all real parties in interest | Raised or reasonably could have raised Applied to subsequent USPTO/district court/ITC action | More likely than not OR Novel or unsettled legal question important to other patents/ applications | 101, 102, 103, 112, double patenting but not best mode |
| Inter Partes Review (IPR) | Person who is not the patent owner, has not previously filed a civil action challenging the validity of a claim of the patent, and has not been served with a complaint alleging infringement of the patent more than 1 year prior (exception for joinder) Must identify all real parties in interest | Raised or reasonably could have raised Applied to subsequent USPTO/district court/ITC action | Reasonable likelihood | 102 and 103 based on patents and printed publications |
| Covered Business Method (CBM) | Must be sued or charged with infringement Financial product or service Excludes technological inventions Must identify all real parties in interest | Office—raised or reasonably could have raised Court-raised | Same as PGR | Same as PGR (some 102 differences) |



Major Differences between IPR, PGR, and CBM

| Proceeding | Available | Applicable | Timing |
|-------------------------------|---|--|--|
| Post Grant Review (PGR) | From patent grant to 9 months after patent grant or reissue | Patent issued under first-inventor-to-file | Must be completed within 12 months from institution, with 6 months good cause exception possible |
| Inter Partes Review (IPR) | For first-inventor-to-file, from the later of: (i) 9 months after patent grant or reissue; or (ii) the date of termination of any post grant review of the patent. For first-to-invent, available after grant or reissue (technical amendment) | Patent issued under first-to-invent or first-inventor-to-file | Must be completed within 12 months from institution, with 6 months good cause exception possible |
| Covered Business Method (CBM) | Available 9/16/12 (for first-inventor-to-file only after PGR not available or completed) | Patents issued under first-to- invent and first-inventor-to-file | Must be completed within 12 months from institution, with 6 months good cause exception possible |



Derivation Proceedings v. Post-Grant Review v. Inter-Partes Review v. Supplement Examination

Encourage early challenge, lower challenging barrier, earlier decision to eliminate uncertainty, replace much more expensive litigation procedure later

| Derivation Proceedings | Post-Grant Review | Inter Partes Review | Supplemental Examination |
|--|--|--|---|
| Forum: Patent Trial and Appeal Board (later applicant v. earlier applicant) or District Court (patentee v. patentee) | Forum: • 3+ member panel at the Patent Trial and Appeal Board | Forum: • 3+ member panel at the Patent Trial and Appeal Board | Forum: • PTO |
| Scope: • Challenge priority of first filer because derived from actual inventor | Scope: • Cancel claims based on 101, 102, 103, 112 (but not Best Mode) | Scope: • Cancel claims based on 102, 103 | Scope: Consider, reconsider, or correct information believed to be relevant to an issued patent |
| PTAB Showing: Application was derived from actual inventor and filed without authorization DC Showing: Patent derived from actual inventor | Supporting evidence allowed: • Patents, printed publications • Expert opinions, affidavits, declarations | Supporting evidence allowed: • Patents, printed publications • Expert opinions, affidavits, declarations | Supporting evidence allowed: • "Information believed to be relevant to the patent" |
| Threshold: | Threshold: | Threshold: | Threshold: |
| PTAB "sufficient evidence" DC civil action | "More likely than not" at least one claim unpatentable OR Novel or unsettled legal question | "Reasonable likelihood" petitioner will prevail on least one challenged claim | None |
| Procedural highlights: | Procedural highlights: | Procedural highlights: | Procedural highlights: |
| PTAB final decision Patent: cancellatio n of claims Application : final refusal of claims DC final decision "relief" | Patent owner can cancel or propose substitute claims at least once Claims cannot be broadened Final determination within 12 months if "good cause" Discovery for "relevant evidence" | Patent owner can cancel or propose substitute claims at least once Claims cannot be broadened Final determination within 12 months, up to 18 months if "good cause" Discovery for deposition of witnesses submitting affidavits or declarations and in "interest of justice" | Removes that information from serving as basis for unenforceability of patent If patent office determines that the information raises a substantial new question of patentability, a reexamination of the patent will be ordered |

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Derivation Proceedings v. Post-Grant Review v. Inter-Partes Review v. Supplement Examination

| Derivation Proceedings | Post-Grant Review | Inter Partes Review | Supplemental Examination |
|---|--|---|---|
| Timing: PTAB: Within 1- year of publication of the later filer's application DC: Within 1 year of issuance of earlier filer's patent DC statute of limitations 10 yrs after the misconduct basis of the proceeding 1 yr after notice to PTO of same | Timing: Within 9 months of issue/reissue Estoppel: "raised or reasonably could have raised" Applies to any claim challenged PTO, ITC, civil actions Cautionary note: because all grounds of invalidity are available, estoppel is broader | Timing: Within 9 months of issue/reissue OR After termination of post-grant review and Within 1 year of commencement of litigation by patent owner Estoppel: "raised or reasonably could have raised" Applies to any claim challenged PTO, ITC, civil actions | Timing: Cannot prevent information from serving as a basis of I/C finding if: I/C was plead earlier in a civil proceeding; or I/C plead as a defense in an enforcement action started before the SE was completed |
| Appeal: directly to Federal Circuit | Appeal: directly to Federal Circuit | Appeal: directly to Federal Circuit | |
| Initiated by: third parties | Initiated by: third parties who have not previously challenged the patent in civil action | Initiated by: third parties who have not previously challenged the patent in civil action | Initiated by: patentee |
| Effective date: March 16, 2013 | Effective date: September 16, 2012 | Effective date: September 16, 2012 | Effective date: September 16, 2012 |
| Applies to: • "first-to-file" applications and patents | Applies to: Pending interferences Business method patents in litigation "first-to-file" patents | Applies to: • All patents | Applies to: • All patents |

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