Doing Business in the United States: Practical Steps for Success in the World’s Largest Life Sciences Market

Foley and ChinaBio Executive Workshop
June 13, 2012
Shanghai, China

Entering the U.S. Market Via Strategic Collaboration, Investment and Acquisition

James C. Chapman, Partner
Foley & Lardner LLP
Introduction - Doing Business in the U.S

- Legal Framework
- Trends in the US Life Science Market
- Top Ten Challenges Facing Chinese Companies “Going Out”
- Common Structures for Entering the US Market

Legal Framework

- Business Entities – corporations, limited liability companies, partnerships
- Foreign Investment –
  - US economy open, no approval required for forming a company, profits and dividends can freely flow abroad (subject to US taxes), no restrictions on interest and royalty rates, financing arrangements are flexible
  - Highly regulated sectors – domestic air transport, banking and broadcasting, national defense, insurance, shipping, mineral rights, energy & utilities - require licenses, citizenship etc.
Trends in the US Life Science Market

- Increase Regulatory Pressures
  - Food and Drug Administration
  - Need for Additional Legal Compliance
- Dramatic Evolution in Process
  - Health Care Reform
  - Personalized Medicine
  - Mobile Health Care
  - New Business Models

Trends in the US Life Science Market (cont.)

- Competition From Emerging Markets ~ China and India
  - Major players in generic drug market
  - Manufacturing, Clinical Trials and R&D Becoming More Cost Effective
  - Skilled Work Force
- Patent Expiration
  - Drugs Resulting in Sales of $120 billion Are Set to Lose Patent Protection in the Next 1-3 Years
Trends in the US Life Science Market (cont.)

- Consolidation and Partnering to Improve Performance and Spread Risk
  - More Consolidation Between Innovative Emerging Companies and Generic Drug Makers
  - More Joint Ventures and Alliances

Financing Challenges

- Public Markets for Life Science Companies Are Weak
- Decrease in Venture Capital Funding - for 1st quarter 2012, Funding for Life Science Companies decreased 22% from the Prior Quarter
- Decrease in Venture Capital Funding - Funding for Life Science Companies decreased 8% from the 1st Quarter 2011.
The Top Ten - Challenges for Chinese Companies "Going Out"

- Lack of Financial Commitment - Short Term vs. Long Term View
- View Employees As "Commodities" who are easily replaceable
- Compensate Employees at Below-Market Rates
- Weak Talent - Speaking Mandarin should not be the only qualification
- Do Not Value Market Knowledge - Value Cheaper Employees Who speak English

The Top Ten - Challenges for Chinese Companies "Going Out" (cont.)

- Are Inflexible - Focus on the "Chinese" model of selling commodities at the lowest prices
- Poor Quality Products
- Very Centralized Decision-Making - Executives on the ground in the US have no decision making authority
- Do not Value Creativity and Initiative-
- Little or No Legal Compliance Infrastructure
Strategic Alliances

- Definition – a cooperative effort whereby each party is involved in the development and sale of a product or service under its own name and logo. There is no co-ownership or separate legal entity formed.

- When are these useful?
  - One time opportunities
  - “Dating” – companies desire a business relationship but do not want to make a serious commitment

Strategic Alliances (cont.)

- Examples –
  - Joint marketing effort where two companies come together to market a solution which includes the products of both parties
  - Joint bid for a project – technology development and integration
Strategic Alliances (cont.)

- Issues –
  - Objectives
  - Duties of the parties
  - Compensation
  - Financial commitment
  - Post-termination competition

Joint Ventures

- Definition An arrangement involving two or more companies or individuals in a partnership for a particular purpose. Each contributing member provides capital, expertise, technology, or other special resources to the venture.
Joint Ventures (cont.)

- Difference between JV’s and Strategic Alliances?
  - JV’s tend require a greater financial and other commitment
  - A new entity is formed
  - Tend to be longer term

- When are these useful?
  - Larger market opportunities as opposed to a single project of bid
  - When each party possesses something the other party needs creating synergy

Joint Ventures (cont.)

- Issues –
  - Objectives
  - Duties of the parties
  - Compensation
  - Financial commitment
  - Competition during the life of the JV
  - Dispute resolution
  - Exit strategy
Strategic Investment

Definition – Where one party seeks to obtain an equity interest in another in exchange for capital

When is this useful?
- When the deployment of capital creates the opportunity for financial return
- When the investor sees an opportunity but does not have the desire or commitment to acquire the entire company
- When combined with cooperation on R&D, product distribution or similar objectives

Process
- Identify objectives
- Identify the type of investment desired
- Establish investment criteria – team, traction, technology, market opportunity
- Establish a means to attract deal flow
- Valuation methodology
- Establish size of initial investment and follow-on
- Establish the investment process – including deal flow, due diligence, legal, tax, accounting, monitoring and assistance
Mergers and Acquisitions

Most common way for foreign companies to enter the US market

When is this useful?
- Buyer wants to enter the market quickly
- Buyer wants have a “head start”
- Buyer wants to acquire something it does not have such as new products or distribution channels

Mergers and Acquisitions (cont.)

Process
- Identify objectives
- Identify the type of target company desired
- Establish purchase criteria – industry sector, size, customer quality, management quality
- Establish a means to attract acquisition opportunities – market research, engage an investment banker
- Valuation methodology
Mergers and Acquisitions (cont.)

- Establish the acquisition process – including due diligence, legal, tax, accounting, monitoring and assistance
- Establish an integration plan – products/services, sales forces, IT systems, accounting and finance and culture

Questions & Answers

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Practical Strategies For Reducing Patent Pendency And Managing Patent Prosecution Costs in the United States

James F. Ewing, Partner
Foley & Lardner LLP

USPTO Data April 2012
**AIA Impact on Costs**

- USPTO is exercising its fee setting authority to set and adjust patent fees to recover the aggregate estimated cost of the patent operation.

- 15% Surcharge (9/26/2011)

- $400 surcharge for new applications not filed electronically (11/16/2011)

- Initial proposal published February 7, 2012

- Final fees implemented February 2013

**AIA Fee Proposal**

<table>
<thead>
<tr>
<th>Description</th>
<th>Current Large Entity Fee (Alternative)</th>
<th>Proposed Large Entity Fee</th>
<th>Dollar Change</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utility—Basic Filing, Search, and Exam (total)</td>
<td>$1,250</td>
<td>$1,840</td>
<td>$590</td>
<td>47%</td>
</tr>
<tr>
<td>Request for Prioritized Exam (Track 1)</td>
<td>$4,800</td>
<td>$4,000</td>
<td>($800)</td>
<td>-17%</td>
</tr>
<tr>
<td>Excess Claims (Independent in Excess of 8)</td>
<td>$250</td>
<td>$480</td>
<td>$230</td>
<td>84%</td>
</tr>
<tr>
<td>Excess Claims (Total in Excess of 20)</td>
<td>$60</td>
<td>$100</td>
<td>$40</td>
<td>67%</td>
</tr>
<tr>
<td>Application Size</td>
<td>$310</td>
<td>$400</td>
<td>$90</td>
<td>29%</td>
</tr>
<tr>
<td>Extensions for Response within 1st Month</td>
<td>$150</td>
<td>$200</td>
<td>$50</td>
<td>33%</td>
</tr>
<tr>
<td>Extensions for Response within 2nd Month</td>
<td>$560</td>
<td>$600</td>
<td>$40</td>
<td>7%</td>
</tr>
<tr>
<td>Extensions for Response within 3rd Month</td>
<td>$1,270</td>
<td>$1,400</td>
<td>$130</td>
<td>10%</td>
</tr>
<tr>
<td>Extensions for Response within 4th Month</td>
<td>$1,380</td>
<td>$2,200</td>
<td>$220</td>
<td>11%</td>
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<tr>
<td>Extensions for Response within 5th Month</td>
<td>$2,690</td>
<td>$3,100</td>
<td>$190</td>
<td>12%</td>
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</table>

### AIA Fee Proposal (cont.)

<table>
<thead>
<tr>
<th>Description</th>
<th>Current Large Entity Fee (Alternative)</th>
<th>Proposed Large Entity Fee</th>
<th>Dollar Change</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request for Continued Examination (RCE)</td>
<td>$930</td>
<td>$1,700</td>
<td>$770</td>
<td>83%</td>
</tr>
<tr>
<td>Notice of Appeal *</td>
<td>$620</td>
<td>$1,500</td>
<td>$880</td>
<td>142%</td>
</tr>
<tr>
<td>Filing a Brief in Support of an Appeal</td>
<td>$620</td>
<td>$0</td>
<td>($620)</td>
<td>-100%</td>
</tr>
<tr>
<td>Filing an Appeal</td>
<td>$0</td>
<td>$3,500</td>
<td>$3,500</td>
<td>102%</td>
</tr>
<tr>
<td>Supplemental Examination</td>
<td>$5,180/$16,120</td>
<td>$7,000/$20,000</td>
<td>$5,700</td>
<td>27%</td>
</tr>
<tr>
<td>Combined Pre-grant Publication and Issue</td>
<td>$2,040</td>
<td>$960</td>
<td>($1,080)</td>
<td>-53%</td>
</tr>
</tbody>
</table>


### AIA Fee Proposal (Cont.)

<table>
<thead>
<tr>
<th>Description</th>
<th>Current Large Entity Fee (Alternative)</th>
<th>Proposed Large Entity Fee</th>
<th>Dollar Change</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance - 1st Stage</td>
<td>$1,130</td>
<td>$1,600</td>
<td>$470</td>
<td>42%</td>
</tr>
<tr>
<td>Maintenance - 2nd Stage</td>
<td>$2,850</td>
<td>$3,600</td>
<td>$750</td>
<td>26%</td>
</tr>
<tr>
<td>Maintenance - 3rd Stage</td>
<td>$4,730</td>
<td>$7,600</td>
<td>$2,870</td>
<td>61%</td>
</tr>
</tbody>
</table>

Cost Saving Tips

- Plan now for increased fees
- Attend to application size and claim count
- Always file electronically
- File applications complete with all formalities
- Avoid extension fees

Cost Saving Tips (cont.)

- Periodically review your portfolio to ensure your assets align with your business objectives
- Abandon or monetize IP that you do not need or that is not core to your commercial position
- A proactive approach is best in dealing with patent agencies
- Consider adjuncts to patent protection
Cost Saving Tips (cont.)

- Choose your countries wisely
- Verify that the subject matter is patentable in the jurisdictions you file
- Consider selecting a single foreign associate in each country to manage similar technologies in your IP portfolio
- Consider the use of a reputable translation service to consolidate all patent translations to reduce expensive translation costs

Cost Saving Tips (cont.)

- Make foreign filing decisions, and provide instructions to your counsel as soon as possible before the 12 month Paris Convention deadline.
  - Ensures enough time to address any specific national requirements and account for time zone or national office closings.
  - Can prepare any country-specific modifications to the specification or claims to put the application in better condition for examination.
Cost Saving Tips (cont.)

- Avoid Requests for Continued Examination
- Engage Examiners early and whenever possible
- Take advantage of fee discounts

Discounting: Micro Entity

- Section 10, establishes a category of “micro entities” which are entitled to reduced (25% of base) fees for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents

- Sole inventors

- Can qualify if all inventors have the majority of their income from a certified institute of higher learning (university) or the application is assigned to such a university

- Not available until USPTO exercises its new fee-setting authority
Post-Issue Fee Information Disclosure Statements

The “Quick Path Information Disclosure Statement (QPIDS) Pilot Program” takes effect May 16, 2012 and will run through September 30, 2012 unless it is extended.

Applicant will be able to obtain consideration of an IDS after the Issue Fee has been paid under certain, limited circumstances

IDS will be placed on the Examiner’s “expedited” docket

QPIDS (cont.)

If the Examiner determines that prosecution does **not** need to be reopened:

- a **corrected** Notice of Allowability will be issued that acknowledges consideration of the IDS
- the RCE fee **automatically will be refunded**

If the Examiner determines that prosecution **does** need to be reopened:

- the RCE will be processed and placed on the Examiner’s docket
- the IDS fee **automatically will be refunded**
- a notice will be issued that prosecution is being reopened
New First Action Interview

- Available now across examining groups
- Request Examiner Interview before first Office Action is received
- Limit on total number of patent claims
- Will not advance application out of turn
- May expedite examination overall

Accelerated/Prioritized Examination in the U.S.

- Patent Prosecution Highway
- Accelerated Examination Program
- Track I Prioritized Examination
- Applicants Age or Health
Patent Prosecution Highway (PPH)

- May 19, 2010, USPTO and SIPO sign memorandum of Understanding on bilateral cooperation on patents
- Focuses on building of work sharing programs, including a bilateral Patent Prosecution Highway (PPH) agreement
- Goal is to improve the administration and effectiveness of the intellectual property systems through the exchange of information.

PPH (cont.)

- The Patent Prosecution Highway (PPH) speeds up the examination process for corresponding applications filed in participating countries by allowing examiners to reuse search and examination results
- Under the PPH program, an applicant receiving a ruling from the Office of First Filing (OFF) that at least one claim is patentable may request that the Office of Second Filing (OSF) fast track the examination of corresponding claims in corresponding applications filed in the OSF
CN-US PPH

- CN application must have at least one claim determined by SIPO to be allowable/patentable
- CN application cannot be a utility model application
- All claims in the US application must sufficiently correspond or be amended to correspond to the allowable/patentable claims in the CN application
- Examination of the US application cannot have begun

PPH Benefits

- Accelerated Examination/Reduced Pendency
  - Examination typically begins within 2-3 months from the grant of a PPH request

- Greater Efficiency
  - More than 70% of PPH cases are allowed. The allowance rate for non-PPH cases is less than 50%
PPH Benefits

- Decreased Costs of Prosecution
  - PPH cases have fewer office actions compared to non-PPH cases.
    - 2.7 average actions in a regular case
    - 1.7 average actions in the PPH
  - It is estimated that in a single application, $2K-13K USD can be saved using the PPH

Japan-US PPH Results

- PPH between Japan and the US has made patent decisions much quicker

  - The time to first action decreases dramatically:

    | Regular cases | PPH cases |
    |---------------|-----------|
    | Japan         | 28.5 months | 1.7 months |

  - The average pendency from first action to final action is 5.5 months (2011)
  - Grant rate: 72.4%
PCT-PPH: CN-US

- Trial period: Dec. 1, 2011 to Nov. 30, 2012

- An applicant receiving a written opinion or an international preliminary examination report from either SIPO or the USPTO that at least one claim in a PCT application has novelty, inventive step, and industrial applicability may request that the other office fast track the examination of corresponding claims in corresponding applications.

Accelerated Examination (AE)

- Applicant may have an application granted accelerated examination status provided certain conditions are met.
- Goal is to complete examination of an application within 12 months from the filing date of the application.
- Applications are placed on an accelerated examination track throughout the entire prosecution in the USPTO.
- Any non-reissue utility or design application filed under 35 USC 111(a) on or after Aug. 25, 2006.
- 371 US national stage applications do not qualify.
AE Key Requirements

- (1) the application must be filed before December 8, 2009;
- (2) the application must contain three or fewer independent claims and twenty or fewer total claims, and must not contain any multiple dependent claims;
- (3) the petition must include a statement explaining how the materiality standard is met if it is not clear on its face from the application disclosure;
- (5) the petition must be filed via EFS-Web; and
- (5) the petition must be accompanied by a request for early publication and the publication fee.

AE Stats

Cumulative AE Petitions Decided on Merits/Substance
(Those that meet formal requirements, Applications filed through 06/30/17,
N = 3707, Status as of 04/09/18)

- Granted: 202, 7.3%
- Approved: 627, 17.1%
- Denied: 3179, 85.6%

Note: Denied (No response from Applicant - Applicant would have moved, but of move not to oppose).
Track I Prioritization

- Available now
- Fee-based expedited examination ($4800/$2400)
- Request must be filed at same time as patent application
- Limited to 10,000 per fiscal year
- USPTO goal to complete examination through final Office Action within one year

Track I: Requirements

- File a new original utility or plant nonprovisional application under 35 U.S.C. § 111(a)
- Not available for a national stage application (submitted under 35 U.S.C. 371) of an international application
- Application must be complete under 37 C.F.R. § 1.51(b)
- File via EFS-Web
- No more than 4 independent claims and 30 total claims or any multiple dependent claims;
- Request prioritized examination and pay fee
Track I: Triggering Termination

- Request for continued examination (RCE)
- Petition for an extension of time for reply
- Request for a suspension of action
- Filing an amendment that results in more than four independent claims, more than thirty total claims, or a multiple dependent claim

USPTO Track I: Performance Through Year-End 2011

- 1,694 Track I petitions submitted
- 98.9% petitions approved
- Avg. 40.8 days to move Track One cases from receipt of petition to completion of pre-examination processing (which includes deciding on the petition)
- 23 allowances
Acceleration Due to Age or Health

- Applications may be accorded accelerated examination status based on an applicant’s age or health

- In order to receive accelerated treatment, applicants must file a petition to make special under 37 CFR 1.102 entitled “Advancement of examination”

- Key requirements include a petition with accompanying evidence showing that:
  1. the state of health of the applicant is such that he or she might not be available to assist in the prosecution of the application if it were to run its normal course, such as a doctor’s certificate or other medical certificate or
  2. that the applicant is 65 years of age or older

Practice Tips

- Familiarize yourself with key programs to accelerate/prioritize examination
- Ask about USPTO pilot programs to improve efficiency in prosecution
- Accelerate prosecution of key applications
- Leverage the PPH to accelerate portfolio development
Overview

- In the United States, an accused infringer can challenge the validity of a patent in court, during an infringement trial.
- However, it is also possible to challenge validity administratively, in the United States Patent & Trademark Office (USPTO).
- This is the so-called U.S. “dual track” system.

Cost of Civil Patent Litigation in U.S.

- Median Cost of U.S. Patent Infringement Litigation in 2011:
  - If $1-$25 million at risk:
    - Through end of discovery ....... $1.5 million
    - Through appeal ...................... $2.5 million
  - If more than $25 million at risk:
    - Through end of discovery ....... $3 million
    - Through appeal ...................... $5 million

Cost of USPTO Patent Challenges

- Median Cost of Ex Parte Reexamination in 2011
  - Through filing of request ...... $10,000

- Median Cost of Inter Partes Reexamination in 2011
  - Through filing of request ...... $35,000
  - Through examiner phase ...... $50,000
  - Through appeal to Board ...... $75,000
  - Through appeal to Court ...... $200,000


Effectiveness of USPTO Patent Reexamination

- Outcome of Inter Partes Reexaminations (1999 – 2011):
  - All patent claims canceled ............ 44%
  - All patent claims upheld ............ 11%
  - At least 1 patent claim changed .. 45%

  - All patent claims canceled ............ 12%
  - All patent claims upheld ............ 24%
  - At least 1 patent claim changed ...64%

Source: USPTO
How Can USPTO Proceedings Reduce Litigation Risk?

1. Stop a patent from issuing in the first place
2. Invalidate the patent after issuance
3. Obtain a verdict of no infringement
   (Because claims were narrowed via amendment or argument)
4. Obtain a stay of the litigation
5. Obtain leverage to settle the litigation
6. Defeat a motion for preliminary injunction
7. Reduce or eliminate damages via intervening rights
   (Because claims were narrowed via amendment)

USPTO Proceedings Available to Invalidate Patents

- Inter Partes Reexamination (AIPA 1999)¹
- Pre-Issuance Submissions of Prior Art (AIA 2011)²
- Post Grant USPTO Trials (AIA 2011)
  - Inter Partes Review²
  - Post-Grant Review³
  - Covered Business Method Patent Review²

¹ Ending September 16, 2012.
² Starting September 16, 2012.
³ Starting March 16, 2013.
Pre-Issuance Submissions by Third Parties

New 35 U.S.C. § 122(e)
- Allows any third party to submit for consideration and inclusion in the record of a patent application
  - any patent, published patent application, or other printed publication of *potential relevance* to the examination of the application
    - (Note: *not* limited to prior art; *not* limited to §§ 102 or 103)
  - a concise description of the asserted relevance of each submitted document
    - (Note: previously prohibited by USPTO rules)

Pre-Issuance Submissions by Third Parties

**Time limits for making submission**
- Must be made before the *earlier of* --
  A. Date a **notice of allowance** is mailed; or
  B. Later of --
    1) 6 months after the date on which the application is first **published** by the Office; or
    2) Date of the **first rejection** of any claim by the examiner
Pre-Issuance Submissions by Third Parties

**Timing Example #1: “A” Date**
- Notice of Allowance less than 6 months after Publication, and First Rejection before Publication

<table>
<thead>
<tr>
<th>Appl. Filed</th>
<th>10 mos.</th>
<th>14 mos.</th>
<th>18 mos.</th>
<th>24 mos.</th>
<th>Notice of Publication</th>
<th>Six months after Pub.</th>
</tr>
</thead>
</table>

* Preissuance submission must be filed before this date

Pre-Issuance Submissions by Third Parties

**Timing Example #2: “B.1” Date**
- Notice of Allowance more than 6 months after Publication, and First Rejection after Publication

<table>
<thead>
<tr>
<th>Appl. Filed</th>
<th>18 mos.</th>
<th>20 mos.</th>
<th>24 mos.</th>
<th>26 mos.</th>
<th>Notice of Publication</th>
<th>Six months after Pub.</th>
</tr>
</thead>
</table>

* Preissuance submission must be filed before this date
Pre-Issuance Submissions by Third Parties

**Timing Example #3: “B.2” Date**
- Notice of Allowance more than 6 months after Publication, and First Rejection before Publication


* Preissuance submission must be filed before this date

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**Advantages**
- Stop a patent from issuing, or cause the applicant to narrow claims
- Relatively inexpensive
- Can be submitted anonymously
- No estoppel

**Disadvantages**
- Maybe too early to know if patent is a risk
- Prior art limited to patents or printed publications (no public use or sale evidence)
- Ex parte
**Ex Parte Reexamination**

**35 U.S.C. § 302 et seq.**
- Any person can request *ex parte* reexamination *at any time* during the period of enforceability of a patent
- Limited to patents and printed publications
- Reexamination will only be ordered if the request raises a “substantial new question of patentability”
  - References previously considered must be presented in a “new light”
- Reexamination will be conducted *ex parte* – without any third-party participation after the request

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**Ex Parte Reexamination**

**Procedure**

<table>
<thead>
<tr>
<th>Reexamination Process</th>
<th>Examiner</th>
<th>PTAB</th>
<th>CAFC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First Appeal</td>
<td>Second Appeal</td>
<td></td>
</tr>
</tbody>
</table>

**Timing of proceedings in 2012**

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Quarter 1</th>
<th>Quarter 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. Months from filing to Order</td>
<td>1.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Avg. Months from filing to FAOM</td>
<td>5.7</td>
<td>6.0</td>
</tr>
<tr>
<td>Avg. Months from filing to NIRC</td>
<td>18.7</td>
<td>18.4</td>
</tr>
<tr>
<td>Avg. Months from filing to Certificate</td>
<td>20.2</td>
<td>21.5</td>
</tr>
</tbody>
</table>

*Source: USPTO*
Outcome of Ex Parte Reexaminations (1981 – 2011):
- All patent claims canceled .......... 12%
- All patent claims upheld ............ 24%
- At least 1 patent claim changed ...64%

Intervening Rights if claims are changed
- Absolute: If claims are changed during reexamination (i.e., not “substantially identical” to original), then all liability is erased for infringement occurring prior to reexam certificate.
- Equitable: Court in equity may provide for continued manufacture, use, or sale of thing patented, for the protection of investments made prior to reexam certificate.

Advantages
- Invalidate a patent, or cause the owner to narrow the claims
- Relatively inexpensive
- Can be submitted anonymously
- No estoppel

Disadvantages
- Prior art limited to patents and printed publications
- Relatively slow
- Ex parte
- No ability to settle
Post-Grant USPTO Trials

Comparison of USPTO Trials to Reexamination
- No Examiner-level phase
- One appeal, directly to Court of Appeals for Federal Circuit (CAFC)
### Post-Grant USPTO Trials

#### Comparison of USPTO Trials to U.S. District Court

<table>
<thead>
<tr>
<th>USPTO Trials</th>
<th>U.S. District Court</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Jury</td>
<td>Lay Juries</td>
</tr>
<tr>
<td>3 Administrative Patent Judges</td>
<td>1 District Judge</td>
</tr>
<tr>
<td>Only validity is considered</td>
<td>Infringement finding possible</td>
</tr>
<tr>
<td>Very limited discovery</td>
<td>Broad discovery</td>
</tr>
</tbody>
</table>

#### Grounds for Challenge

- **Inter Partes Review**
  - Patents or printed publications under §§ 102, 103

- **Post-Grant Review & Covered Business Method Review**
  - §§ 101, 102, 103, 112 (not best mode), 251
    - E.g., public use, on sale, written description, enablement, indefiniteness
Post-Grant USPTO Trials

Filing Windows

- Post-Grant Review
  - Within 9 months of either patent grant or broadening reissue
- Inter Partes Review
  - After 9-month Post-Grant Review window above, or conclusion of any Post-Grant Review, whichever is later
- Covered Business Method Patent Review
  - Only if petitioner, real party in interest, or privy has been sued for or charged with infringement of “covered business method patent”

Post-Grant USPTO Trials

Stages of Trial
Post-Grant USPTO Trials

Increased Likelihood of Litigation Stays?

- Courts look at whether USPTO proceeding is started early in litigation and how long the USPTO proceeding is expected to take.
- New Post-Grant and Inter Partes Review should increase chance of litigation stay:
  - Must be brought within 1 year of litigation.
  - Must be concluded within 1 year.

Estoppel: A written decision by the PTAB in a Post-Grant Review or Inter Partes Review will result in estoppel against:

- **Who?** Petitioner, Real Party in Interest, and Privy.
  - **Where?** In any subsequent USPTO Proceeding (Reexamination or Trial) or Civil Action (District Court or International Trade Commission).
  - **What?** Regarding any issue the Petitioner “raised or reasonably could have raised” in the Post-Grant Review or Inter Partes Review.

Therefore, Petitioner must raise all possible arguments.
# Post-Grant USPTO Trials

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>Invalidate a patent, or cause owner to narrow claims</td>
<td>Post Grant Review must be brought within 9 months of grant</td>
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<tr>
<td>Adversarial</td>
<td>Inter Partes Review must be brought within 1 year of suit</td>
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<tr>
<td>Fast decision (1 year)</td>
<td>Estoppel in future against issues petitioner “raised or reasonably could have raised”</td>
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<td>Less expensive than litigation</td>
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<td>Question the other side’s experts</td>
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<tr>
<td>Settlement</td>
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Post Grant Review must be brought within 9 months of grant.
Inter Partes Review must be brought within 1 year of suit.
Estoppel in future against issues petitioner “raised or reasonably could have raised”.

## Summary

### Patent Lifecycle with USPTO Challenges

- Patent Application Filed
- Potential Inter Partes Review
- Patent Issues
- Possible Post-Grant Review Process & Appeal
- Patent Expires
- Potential Section 18 Proceeding for BMPs
- Motion to Stay (Preliminary)
- Appeal Ends
- Patent Suits

**Note 1:** There is an immediate right to interlocutory appeal to CAFC from district court decision on Motion to Stay for a Section 18 proceeding.

**Note 2:** There is a range of possible pendiencies for a Section 18 proceeding: shorter if the USPTO can meet the statutory deadlines, and longer if not. This may depend on the USPTO receiving sufficient funding to properly carry out Section 18 proceedings.

**Note 3:** Completion date depends upon pendiencies in the Section 18 proceeding.
Achieving Your Objectives

- **Patent Owner**
  - Prepare case to defend early (line up experts and supporting data to use in future).
  - Consider dependent claims during original prosecution (avoid need to amend later).
  - When attacked, fight back.

- **Third Party Requester**
  - Closely monitor competitors’ pending applications.
  - Evaluate weaknesses of existing claims.
  - Evaluate original claim construction.
  - Prepare experts and evidence in advance.

Questions & Answers

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