PATENT PROTECTION IN 2021
A PRIMER

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Patent Overview

What is a Patent?

- A Legal Instrument Defining an Intellectual Property Right
  - No protection of idea *per se*.
  - Protects idea which is embodied in an article of manufacture, a composition of matter (e.g., a gene sequence) or a method of use (e.g., a therapeutic treatment)
  - Does not protect mechanism of action although mechanism may be helpful for addressing obviousness issues

What Rights Does a Patent Confer?

- Exclusivity to Make, Use and Sell Claimed Invention for Term of the Patent
- Commercial Translation into Increased Revenues and Profitability

Why Patent? Economic Considerations

- Oftentimes only way to commercialize a product, process or therapeutic Treatment
- Sina qua non for investor group participation/investment
- Revenues to the University/STC for Further Research
- Royalties to the Inventors

When Do We Patent?

- Anytime we develop a commercially viable invention which is new (novel) and non-obvious- preferably, before publication!

Patentable Subject Matter

New (Novel) and Non-Obvious Useful Articles of Manufacture, Methods of Making and Using Articles of Manufacture

Articles of Manufacture

- **Apparatus- assay systems Flow Cytometry, etc.**
- **Chemical Compounds *per se***
- **Chemical Compositions**
  - **Pharmaceutical Compositions**
  - **Compositions of Compounds-Combination Therapies**
  - **Drug Delivery Systems-Sustained and Controlled Release Systems**

- **Biological Products**
  - **New Proteins/Peptides**
  - **Isolated DNA and cDNA encoding for Proteins/Peptides**
  - **Vectors such as Plamids**
  - **Antibodies**
  - **Cells**
  - **Animals**
  - **Assays System Components and Kits**

Methods of Making Articles of Manufacture Or Producing an Intended Result

Methods of Making

- New Chemical Synthetic Methods- Methods and Intermediates

- Methods of Producing Proteins/Peptides and Other Biological Products (cDNA)

- Methods of Isolating and Purifying Products (Receptors, etc.)

Producing an Intended Result

- Methods of Identifying Active Agents-Using Assay Systems

- Methods of Treating (Therapeutic Methods)

Generally, Individual Indications

- New Use of Old Compounds or Compositions- Repurposing Efforts

Seeking Patent Protection

United States Patent Protection

Non-United States Patent Protection

Each Sovereign State has its own patent laws which may or may not be analogous to the laws of the United States

PCT Applications

- Attempt to Harmonize Various Patent Laws and ease administrative burden of filing in numerous jurisdictions

- Most Commercially Relevant Jurisdictions with the Exception of Taiwan and Argentina

United States Patent Protection

Invention Must Be Useful (Utility), New (Novel) and Non-Obvious

-Utility-The invention Must Be *Useful*

-Novel-*Identical* Invention Must Not Be Found in the Prior Art

-Non-Obvious-Invention Must Not Be Obvious Over the Teachings of Prior Art- Assserted As Inventive Step Outside US

Novelty and Non-Obviousness of Invention Always Viewed with Reference to Prior Art

Patent Applications are filed as Provisional or Non-Provisional

Non-United States Patent Protection

Same General Rules of Patentability Apply Outside the United States

-Utility, novelty and non-obvious
-Standards and Scrutiny May Vary
-Most Non-US Jurisdictions Are Absolute Novelty Jurisdictions

Priority Applications

-Can establish filing date based upon priority application

-International Application must be filed within one year of the original U.S. application filing date and claim priority from that application
Otherwise, Applicant loses the benefit of priority

Absolute Novelty

U.S. and Most foreign jurisdictions are absolute novelty jurisdictions
In the United States-Inventor has until one year after publication of his or her invention to file an application in the United States

WHAT IS PRIOR ART?

Any Disclosure of the Invention in the Public Domain

Publications-As of the Date Mailing the Journal Article or Posting of Abstract on a Website
Submission of article not a publication

- Seminar Abstracts and Conference Publications
Poster Sessions

- Department Seminars -Thesis Defense (Public or Closed)

- Approved Grant Proposals Available Through FOIA

- Public Use of Invention

- Commercialization of Products Embodying the Invention – Anywhere in World
Invention On Sale or Offered for Sale- Does Not Apply To Licensing

Preparing and Filing a United States Patent Application

Two Types of Applications

Provisional Application

Regular Non-Provisional United States Patent Application

For All Purposes, Assume That the Requirements for Filing Provisional and Regular United States Patent Applications are *IDENTICAL*

Provisional Patent Application

-Delays examination of regular U.S. application and extends term

-Establishes priority for U.S. and foreign filing and allows the subsequent U.S. application to have a 20 year term from its filing date

Provisional application must meet the same statutory requirements of a regular U.S. Patent Application- OTHERWISE RIGHTS MAY BE LOST!

Contents of a Patent Application

Filed (Original) Patent Application Looks Similar to an Issued Patent

- -Except for the Claims

Most Important Part of the Application is the *Claims*

- The Claims Define the Invention In Clear and Concise Words- Establishes Inventorship
- The rest of the application provides support for the claims

A Patent Application Must Have the Following:

- -A Disclosed Utility
- -An Adequate Written Description of the Invention
- -Must Show One or Ordinary Skill How to Make and Use the Invention Without Engaging in *Undue Experimentation*
  - -Molecular Biology- Deposit Requirement
  - -For non-U.S. protection -best to make a deposit before filing the patent application

Disclosure of Unexpected or Surprising Results

- -Not a requirement
- -May Assist in Seeking Allowance of Claims
- -May Wish to Reasonably Speculate On Biological Activity
- -Synergistic Combinations

Best Mode – No Longer Required in US- but is in Canada

Examination of Patent Application

Notice to File Missing Parts

Assignment of Art Unit and Examiner

Examiner Conducts Search of Prior Art

- **Applicant Must Cite Known Prior Art to Examiner**
- **Make Sure All Relevant Art Known is Cited**

Examiner Issues First Office Action

-Restriction Requirements-More than One Invention
Refile restricted out claims in divisional applications

-Rejection of Application on Statutory Grounds
-Formal Rejections
-Substantive Rejections

Applicant Responds to Office Action

Responding to the Office Action

Formal Rejections/Objections

-Minor, Generally Easily Addressed Rejections/Objections

Substantive Rejections

1. **Insufficiency of Disclosure-Enablement/written description**

2. **Not Inventive Over the Teaching of the Prior Art**

   - Anticipated (No novelty)- Single Prior Art Reference
   - Obvious Over the Art- One or More Art References

Applicant Responds

-Defeat Insufficiency of Disclosure-Show Enablement/Written Description Using Teachings in Specification or Prior Art

-Defeat Anticipation Rejection-Show Invention Not Found in Single Prior Art Reference- Inherency

-Defeat Obviousness Rejection

-Combination of References Does Not Teach Invention or Teaches Away
-Claimed Invention Represents an Unexpected or Surprising Result
-Invention Meets a Long-Felt Need in the Art
-No contemporaneous Invention-Despite Intense Research Efforts, Others Failed To Come Up With Same Invention
-Others In Art View Invention With Considerable Esteem
Declarations from Colleagues
-Commercial Success of invention

Policy/Practice In the US PTO

Can Be Difficult to Have Broad Claims Issued Without Experimental Support
- **As to breadth**

Obviousness Rejections Can Rely On Experience and General Knowledge of Routineer- No Need for Specific Documentary Support from Directly Analogous Prior Art

Many More Inherency/Novelty Rejections- PTO Wants to See Experimental Support for Non-Inherency

Many More Restriction Requirements- and Species Limitations

Review of Patentability Decisions by Review Committees
- **Patent Trial and Appeal Board PTAB**
- **District Court Eastern District of Virginia More Flexibility then Federal Circuit**
- **United States Court of Appeals for the Federal Circuit**
  - **Evidence Limited to Record**

Key Patent Issues for Life Sciences

File a provisional application before you publish- Preferably meeting all requirements for patentability

But- costs and timing

Make sure application has sufficient support and claims the invention.

Claim Appropriate Breadth for Invention

Avoid claims which are invitations to experiment

Description of Invention Must Support Application

-Chemical syntheses- Support individual species

- Biotechnology Patent Applications- Provide an Adequate Enablement/Written Description to support the breadth of the claims

General Rule- provide as much disclosure as possible and hope for the best- fact driven inquiry

Key Patent Issues (Cont'd)

Don't Disclose Invention to Anyone Until After you file

Document Invention (Inventorship Issues)

When Conducting Research-Document Inventions in Notebooks

"Read and Understood"

Document/Memorialize Group Meetings

Material Transfer Agreements-
Agreements to Share Compounds

Dealings with Colleagues Industry/Universities
"Creative Colleague"

Leahy-Smith America Invents Act 9/16/2011 List of Changes

1. **"First to File"**
   - Prior Art Definition
   - Disclosure "Grace Period"
2. **Pre-Issuance**
   - Fee Increases
   - Micro-Entities
   - Prioritized Examination
   - Third Party Submissions
3. **Post-Issuance**
   - Existing Procedures- *Ex Parte* Reexamination and Reissue
   - Inter Partes Review
   - Post Grant Review
   - Derivation Proceedings
   - Supplemental Examination
   - Third Party Submissions
4. **Litigation**
   - Prior Use Definitions
   - Best Mode Requirement
   - False Marketing

"First to File"

- The AIA changed the current U.S. patent system from a "first to invent" system to a "first to file" system. This is consistent with patent laws throughout most of the world.
  - A "first to invent" system gives priority to the first to invent. Evidence supporting conception of the claimed invention prior to the filing date of the application may be considered to determine the first inventor of the invention.
  - A "first to file" system gives priority to the application/invention with the earliest filing date.
- Effects:
  - Applicants will no longer be able to rely upon an earlier date of conception when prior art has an earlier date then the effective filing date if the prior art is not their own discloser.
  - An inventor who waits to file an application may risk losing his or her patent rights to an inventor who invented later but filed first.

Effective Date was March 16, 2013 and applicable to any application with an effective filing date on or after that date.

Definition of Prior Art

- The AIA modifies what constitutes anticipatory prior art:

> **§ 102. Conditions for patentability; novelty**
>
> "(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> "(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
>
> "(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

- Effects:
  - The date that prior art is effective is determined by the earliest effective filing date ("first to file").
  - The inclusion of the language "otherwise disclosed to the public" allegedly expands the type of prior art that can be used to prevent a patent from issuing or that can be used to invalidate a patent in a civil action.
  - Prior public use or prior sale anywhere qualifies as prior art (prior public use and sale is no longer limited to the U.S.).

Effective Date: March 16, 2013 and applicable to any application with an effective filing date on or after that date.

Disclosures : "Grace Period"

- The AIA modifies the conditions for "swearing behind" a disclosure:

§ 102. Conditions for patentability; novelty

''(b) EXCEPTIONS.—

''(1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION. —A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

''(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

''(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly.

- Effects:
  - An applicant can only "swear behind" a disclosure when the disclosure is made one year or less before the effective filing.
  - The disclosure must be made by the inventors or another who disclosed the subject matter directly or indirectly from the inventors.(Previously, Inventors could "swear behind" a disclosure regardless of the author.)

Effective Date: March 16, 2013 and applicable to any application with an effective filing date on or after that date.

Prioritized Examination

- Prioritized examination can now be obtained for utility and plant patent applications.
- The USPTO states the "goal is to provide a final disposition within twelve months, on average, of prioritized status being granted. "
- A maximum of 10,000 requests will be granted per fiscal year, although the USPTO may choose to revise that cap in the future.
- The cost is $4,800. ($2,400 for small entities.)
- Prioritized applications may have no more that 4 independent claims and 30 claims total.
- The USPTO may "provide for prioritization of examination of applications for products, processes, or technologies that are important to the national economy or national competiveness without recovering aggregate cost of providing such prioritization."
- Initial Observations evidenced a practical *slow down* of applications- recent evidence suggests that the Patent Office has become better at administering these applications.

Effective Date: September 26, 2011.

Third Party Submissions

- Any person at any time may cite to the USPTO in writing:
  - Prior art consisting of patents or printed publications which that person believes has a bearing on the patentability of any claim of the patent.
    - The submission will become part of the file if the person citing the prior art explains in writing the pertinence and manner of applying the prior art to at least one 1 claim

      (Original provision is unaltered by the AIA)
  - Statements of the patent owner filed in a proceeding before a Federal court or the USPTO in which the patent owner took a position on the scope of any claim of a particular patent.
    - Only usable to determine proper meaning of a patent claim in reexamination, post grant and inter partes review proceedings.

      (New provision under the AIA)

International Applications

To Establish Priority of a US Provisional or Non-Provisional Application

Paris Convention

Filed within 12 months of original priority application

directly into the individual jurisdiction-

May only be relevant today to Taiwan, Argentina, Some Middle Eastern

Patent Cooperation Treaty (PCT)

Filed no later than one year from earliest priority application

Designates by Default 153 PCT Member States

Covers most commercially relevant jurisdictions except as above

Allows filing of application in all Member States Until 30/31 Months after date of priority application- Generally, about 18 months after filing PCT application

Non-United States Patent Protection

Same General Rules of Patentability Apply Outside the United States

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-Standards and Scrutiny May Vary
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Priority Applications

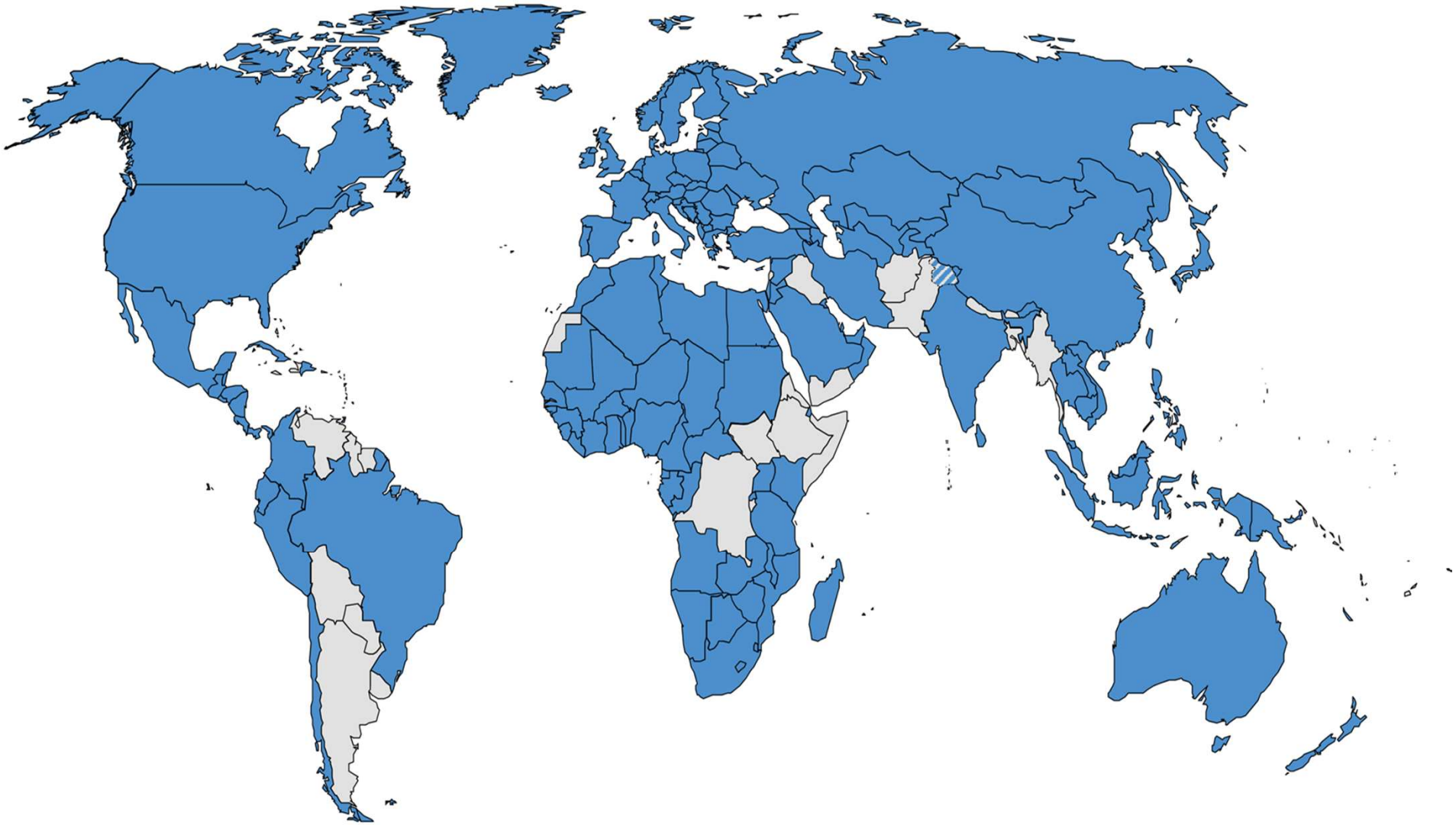
-Can establish filing date based upon priority application

-International Application must be filed within one year of the original U.S. application filing date and claim priority from that application
Otherwise, Applicant loses the benefit of priority

Absolute Novelty

U.S. and Most foreign jurisdictions are absolute novelty jurisdictions
In the United States-Inventor has until one year after publication of his or her invention to file an application in the United States
Japan, Mexico, Argentina, Australia, Philippines, S. Korea, Brazil Singapore

The Patent Cooperation Treaty has 153 Contracting States



PCT Applications

Important Features

At Time of Application-

Choosing the Search Authority

-Cost/Competence

Russian Search Authority Now Most Cost Effective

During International Application Phase

Unity of Invention- Costs for Additional Inventions

Amendments

Article 19 and Article 34 Search Report/Written Opinion

Amending Applicants/Inventors

Nunc Pro Tunc Assignments

National Phase

Filed at any time prior to expiration of 30/31 months after priority application filing date

http://www.wipo.int/pct/en/texts/time_limits.html

Most Relevant Jurisdictions

United States 30 Months- Flexible
Europe 31 Months- Flexible
China 30 Months but can extend to 32 Months for a fee
Japan 30 Months- Rigid
Eurasia/Russia 31 Months
India 31 Months
Brazil 30 Months
Australia 31 Months
Indonesia 31 Months
Malaysia 30 Months
Canada 30 Months- Extremely Flexible
Mexico 30 Months Rigid

NON-US FILINGS PRINCIPAL CONSIDERATIONS

Cost- Especially Translations, Prosecution (Ease) and Annuities
The Impact of Foreign Account Tax Compliance Act (FATCA)

Business Opportunity- Partnering/License Opportunities-
Local- Compulsory?

Jurisdictional Tenor/Quirks - Patent Friendly or Averse

Patent Enforcement- Rule of Law; Court System
Does Patent Office and Court System Afford Protection

Political Considerations
Often Influencing Prosecution/Scrutiny Even When Unstated

National Phase- Individual Jurisdictions

UNITED STATES

- AIA In full Effect Since March, 2013 Lots of Rules Changes
- Change in Prior Art- Now Absolute Novelty With Carve-Out Exceptions"
- Prosecution has been hastened somewhat
- "Trolls" huge impact on level of evidence
- Experimental Evidence in Declaration Form Often Required
- Allows Method of Treatment Claims

EUROPE

- Rules for Unity of Invention and Divisional Applications
  - Far Less Draconian then in Recent Past
- Written Description/ Support for Claims- Still Somewhat Draconian
  - Diversity of Language Issue- Literalist Interpretation
- Expermental Evidence Can Be Submitted in Informal Form
- Costs for Registering Issued European Application- significant decrease
  - Not as many jurisdictions require translations
- No Longer Swiss-style Use Claims- Compositions for Use In Treatment of…

National Phase- Individual Jurisdictions

CHINA

- Less Patent Averse Than Recent- Considerable Scrutiny of Applications
- Written Description Important Some Flexibility on Submission of Post-Application Data- Recent Change in the Law
- Inconsistency, but getting better
- Much Better Experience With Newer Technologies
  - Both Examiners and Associates
- No Amendments filed until Voluntary Amendment/Request for Exam
- Allows Swiss-style Use Claims

JAPAN

- Increasing Flexibility in issuing broader applications
- Increasing Flexibility in allowing Post-Application Data
- Written Description Far Less Onerous than In Other Jurisdictions
- Costs for Claims has substantially increased- but can reduce costs at Request for Examination Substantially
- Allows Swiss-style Use Claims

National Phase- Individual Jurisdictions

Eurasia/Russia

- Eurasian Patent Office much more patent friendly than Russian Office
- Oftentimes will get other than a Russian Patent Examiner
- Written description less problematic and somewhat flexible although emphasis is placed on examples- especially in chemical cases
- Will allow Swiss-style use claims
- Expensive to file; Less expensive than in recent past to register
- Recommendation- File in Eurasian PTO and Designate only Russia or File Russian Federation Patent from Belarus (Minsk)

INDIA

- Relatively inexpensive to file. Can file in English.
- Long-winded patent proseuction- years to seek allowance
- Compositions and Compounds Patentable as well as some methods
- No method of treatment or Swiss-Style Use
- Difficult to Practice Invention Without Local Partner
- Foreign Filing License Required for PCT applications- If Inventor is a resident of India- even where invention was made in US or other non-Indian jurisdiction

National Phase- Individual Jurisdictions

Brazil

- Expensive and Difficult Jurisdiction- Somewhat Patent Averse
- No Method of Treatment Claims, But Swiss-style Use Claims Accepted
- Claims must be established from first filing- limited amendments
- Prosecution is often nit-picky, limiting
- Will Likely Be Forced to Deal with Local Company- Unless Mega Corporation
- After Patent is Issued- Shunted Into Ministry of Trade Regulatory Body

Australia

- Overall, inexpensive because proceedings conducted in English
- Generally, patent friendly and prosecution relatively easy although recently has gotten more difficult-
- Will Accept Swiss-style use Claims and Method of Treatment Claims
- Competent on New Technologies- especially in Medical and Biotech
- Obviousness scrutiny has become more signicant as has Examiner's inquiry

National Phase- Individual Jurisdictions

Indonesia

- Large, Commercially Relevant Jurisdiction 230+ Million Population
- Generally Inexpensive Except for Language/Translation Issues
- Prosecution Less Flexible Given Rules Changes
- Swiss-style Use Claims No longer Patentable- Must be Composition
- More Licensing Activity- Especially in Medical Technologies

Malaysia

- Similar to Indonesia in size and relevance
- More Expensive Than Indonesia
- Prosecution Relatively Flexible and Straight Forward
  - Broad Coverage Often Possible
- Swiss-style Use Claims Patentable
- If Filing in Malaysia- Should Consider Singapore and Thailand As Well
- Can register claims of US Patent in Malaysia- Registration Jurisdiction

National Phase- Individual Jurisdictions

CANADA

Inexpensive and Flexible Patent Policies- English
Similar Prior Art Construction to US
Will Track US Prosecution Closely
Swiss-Style Use Claims Accepted
Note- Still Requires Best Mode- Unlike US

MEXICO

Inexpensive and Flexible- but Translation Costs
Broad Coverage Possible- Generally Will Accept US Prosecution
Prosecution is Straight Forward and Inexpensive
When patent is allowed- Expensive Up Front Payment of Annuities
Swiss-Style Use Claims Accepted