

Agenda

- · Foreign Filing Options
- · Specific country focus
 - Europe
 - Australia
 - Brazil
 - Canada
 - China
 - Japan



Foreign Filing Options

- Direct filing (Paris Convention)
- Filing a Patent Cooperation Treaty (PCT) application
 - Delays direct filings for up to 30 months from the earlier priority date
 - 152 contracting states



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Countries that are not members of the PCT (as of March 2019)

PURPLE – Country also not part of the Paris Convention



Foreign Filing Options

253,000 PCT applications filed in 2018Top 10 PCT filing

countries

Country	Applications Filed	Change from 2017
U.S.	56,142	↓ 0.9%
China	53,345	↑ 9.1%
Japan	49,702	↑ 3.1%
Germany	19,883	↑ 4.9%
Korea	17,014	↑ 8.0 %
France	7,914	↓ 1.2%
UK	5,641	↑ 1.3%
Switzerland	4,568	↑ 1.8%
Sweden	4,162	↑ 4.7%
Netherlands	4,138	↓ 6.6%



Foreign Filing Options

Top 10 University PCT filers

University	Origin	Number of Published Applications
University of California	U.S.	501
Massachusetts Institute of Technology	U.S.	216
Shenzhen University	China	201
South China University of Technology	China	170
Harvard University	U.S.	169
University of Texas System	U.S.	158
Tsinghua University	China	137
Seoul National University	Korea	137
Stanford	U.S.	121
China University of Mining and Technology	China	114





	Drafting
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Patentability - Not An Invention

- Methods of therapy, surgery, diagnosis
 Practiced on the human or animal body
- Can get 1st medical use claims researcher finds a first medical use of a compound (can be a known compound)
- "Compound X for use in the treatment of the human or animal body"

 ...and/or 2nd medical use claims compound is known in medicine but researcher finds a new condition that can be treated
- "Compound X for use in the treatment of condition Y"

 Condition Y is named condition, not specified by function
 "...in the treatment of condition X"

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"...in the treatment of a condition caused by inhibition of the abc pathway."

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Patentability - Not Patentable

- · Methods of doing business
- · Computer programs
- Excluded "per se" can be OK if they have some "technical" content
- Product/method having a **technical character** is not excluded from patentability – even if implemented by computer software



Assignments

- Chain of title at time of filing PCT is vital in Europe
- Get assignments from all inventors before filing PCT
- Not correctable afterwards, e.g. ex post facto assignment
- Can lose priority date in Europe
 - · Fatal if published (even self-published) in priority year



Drafting

- Strict assessment of basis for amendment at EPO
- "clear and unambiguous disclosure" some examiners interpret this as "explicit wording" which is wrong but can be a difficult argument
- Include sensible fallbacks on drafting
- Include basis for combinations of features
- · Include basis for features independently
- · Include basis for multiple dependent claims
- Include advantages associated with features "In some embodiments variable X is Y. In those cases the reaction is found to provide a higher yield"



Coversheet Priority Filings

- From an EP perspective, avoid if possible
- · Difficult to find language for EP claims
- (Very) often problems with basis for amendment in prosecution
- Strict assessment of priority can lead to loss of priority date fatal if published in priority period (which they usually are!)



Filing & Prosecution



General Features of the EPO

- · Central application and examination
- Choice of EP states for "validation" shortly after grant
- · Some translations required
 - Some countries just claims
- Some countries whole application
 High claim fees & page fees cut down claims to 15 to avoid



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- Strict requirement for basis for amendment in original application (the PCT)
- · Sometimes incompatible with US approach
- Examiner will often ask for identification of specific paragraphs/passages (keep in mind when sending instructions)
- · Original drafting of PCT/priority application is important



Examination

- Novelty absolute novelty can't "swear behind" own art
- Inventive Step ("obviousness") EPO "problem/solution" approach
- Basically identify the benefit associated with your novel feature(s) & show that it would not have been expected to occur
- Different to "does not suggest or teach"
- Examiner interviews relatively uncommon, usually by telephone



Oral Proceedings

- Appointed by EPO where progress has halted
- Difficult to change date
- Hearing in person (Munich/Hague)
- Fallback positions ("Auxiliary Requests") in advance & amendments possible (usually) on the day
- Decision on the day
- · Can be appealed
- Can often avoid by judicious amendment/examiner discussion in advance



Third Party Observations

- At any stage during EP proceedings
- Most effective during early-mid stages of examination
- Comment on patentability & provide documents
- Can be anonymous
- No estoppel can still argue same issues & same docs at opposition
- Doesn't make cited docs harder to use later
- Relatively cheap no official fee; attorney time
- · Less effective for complex issues



Grant

EP Grant Stage

- Confirm text for grant (proposed by EPO)
 - Can still propose (small) changes
- Translate claims into French & German
- Choose countries for validation (short deadline following grant)
- Check ownership <u>much</u> cheaper to record any changes at this stage than after grant



Post-Grant Post-Grant	
Opposition Deadline = 9 months from formal grant date Can be "Straw Man" All documents and arguments available – no estoppel Raise all arguments & objections – difficult/impossible to introduce later EPO sets time period for reply (4 months) EPO sets date for Oral Proceedings & issues preliminary opinion – also date for final written submissions All parties final written arguments – proprietor "Auxiliary Requests" Oral Proceedings – Opposition Division (3 members) Decision on the day & in writing later Appealable	
Limitation • Central post-grant limitation possible @ EPO • Must be a "limitation" of granted claims	

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Only examined for added matter and clarity

Revalidation needed (translations etc.)
 Not possible if opposition in process
 Can be useful to prepare claims for litigation

If accepted, effect is as if granted with that scope (ex tunc not ex nunc)

Summary

- Ask your US counsel re: patentability
- Take care when drafting fallback positions
- · Mention advantages in original filing
- · Great care with chain of title
- Provide basis from original when sending instructions
- Costs can be high at grant choose countries
- Consider TPO if competitor application is pending
- If in doubt ask your US counsel!





Patent Protection in Australia, Brazil, Canada, China and Japan

Australia

- · What is patentable?
 - Biological inventions:
 - Patentable

 - entable
 Isolated bacteria, cell lines, hybridomas, some related biological
 materials and their use
 Genetically manipulated organisms, genotypically or phenotypically
 modified living organisms, for example, genetically modified bacteria,
 plants and non-human organisms
 Isolated polypeptides and proteins
 Therapeutic, surgical and diagnostic methods for the treatment of
 humans and animals provided a sample is removed from the body
 Instantable

 - Not patentable

 Human beings and methods for their generation

 Gene sequences, DNA, RNA or nucleic acid sequences

 Irrelevant whether the genetic material was isolated or man-made



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- · Computer-Implemented Inventions:
 - Question is whether what is claimed "as a matter of substance" meets the requirements for a manner of manufacture
 - · To meet this requirement, an invention must relate to an artificially created state of affairs that are of economic significance
 - · Cannot be a mere scheme, abstract idea or mere information
 - Consideration goes beyond the form of the words used in the claims
 - Substance to be understood in the context of the specification as a whole and the relevant common general knowledge and prior art



Australia

- · Business methods and software are patentable
 - · No statutory exclusion exists in Australia to obtaining patent protection for business method or software inventions
 - Practice in Australia is similar to European practice
 - · Primary consideration is:
 - Does the claimed invention solve a "technical" problem existing in the art versus, for example, defining a mere scheme or plan (e.g. arrangement or presentation of data etc.)
 - · Some links to inventive step as in European practice



Australia

- Additionally:
- Additionally:
 Including a requirement in the claim to implement the software/business method using a computer is not in itself enough to establish a manner of manufacture
 Not just a question of whether a "physical" element exists in the claim, but whether a technical problem is addressed and solved by the claimed invention.

 Where the claimed invention involves computer implementation of a software/business method, if the functioning of the computer is enhanced irrespective of the data being processed this can be quite persuasive in establishing a manner of manufacturer.

 IP Australia practice: Software inventions are generally easier to argue in relation to the manner of manufacture requirement than business methods which are rarely patentable (in consideration of the requirements listed above)



Australia

- · Nuts and bolts
 - · Entry deadline: 31 months from priority date (a retrospective extension of time is available when the deadline is inadvertently missed)
 - · Translation required: No (if application is filed in English)
 - What is required: Copy of PCT application or publication number; no Power of Attorney needed
 - **Grace Period:** Yes 12 months for disclosures of the invention made by the Applicant, with the consent of the Applicant or without the consent of the applicant; complete application (e.g. PCT application) must be filed within that period, not a U.S. provisional

Australia

- · Requests for Examination: Formal request for examination must be filed within 5 years of application filing date
- Divisional applications: Voluntary divisionals are allowed; can be filed at any time but must be filed at the latest within 3 months of advertisement of acceptance (i.e., allowance)
- · Methods of Treatment claims allowed? Yes
- · Cost (filing and prosecution: 5-10K (page numbers are not relevant - no additional charges or official fees)
- Time line for grant: 4-6 years
- · Allowance rate: Greater than 90%



Australia

•Filing Tips

- Comply with AU "best method" requirement: Include best method of performing the invention described in the application known to the Applicant at the time of filing (ground of opposition/revocation used successfully in recent
- Excess claims fees are payable at acceptance (allowance) not at the time of filing or when requesting examination based on the number of accepted claims (start with a full number of claims at filing and reduce them during
 - · Multiple dependent claims are allowed and and do not effect excess
- Voluntary amendments are possible at any time during prosecution including switching to new and unsearched claims



Australia

Filing Tips

- Use postponement of acceptance provisions: Request at any time (e.g. when requesting examination) allowing examination to progress but preventing application from being accepted (i.e. allowed) until postponement of acceptance is formally withdrawn can be useful for numerous purposes (e.g. progression of foreign prosecution, allowing reduction of examined claims to avoid incurring excess claims fees)
- Expedited prosecution: Global Patent Prosecution Highway (GPPH) and Patent Prosecution Highway (PPH) available, but Australia's internal expedited examination provisions are simpler and more cost-effective to use
 - Can expedite AU prosecution, get an allowance, and use to gain an expedited examination status in other countries via GPPH/PPH



Brazil

- What is patentable?
 - · Biological inventions:
 - Patentable
 - Isolated bacteria, cell lines, hybridomas, some related biological materials and their use
 - Novel, isolated DNA and proteins
 - Genetically manipulated organisms, genotypically or phenotypically modified living organisms, for example, genetically modified bacteria
 - Diagnostic methods for the treatment of humans and animals provided a sample is removed from the body
 - · Not patentable
 - Human beings and methods for their generation
 - Human beings and methods for their generation
 Plants (including genetically engineered plants) and transgenic animals.



Brazil

- Business Methods and Computer-related inventions:
 - Business methods per se are not patentable in Brazil
 - Technical processes that improve the implementation of a business
 - method are patentable

 Example: A method for authenticating a user for a financial transaction and a method for increasing the security of bank accounts both constitute patentable subject matter
 - · Analyze the claim as a whole



Brazil

- Software (source code) per se is not patentable in Brazil
 - Any technical result obtained from software can be patented (e.g., a method carried out by software instructions and systems or devices affected by software instructions)
 - · INPI's Examination Guidelines state:
 - **ITS EXAMINITATION GUIDENINES STATE:
 * An industrial creation process or product associated with the process implemented by a computer program, which solves a problem found in the technique not solely concerning the way in which this computer program is written, can be considered an invention."



Brazil

- · Nuts and bolts
 - Entry deadline: 30 months (not extendible)
 - **Translation required**: Yes, into Portuguese which must be filed within the time limit of national phase entry
 - What is required: Minimum at the time of filing (in order to get a filing date) Request form; information regarding the Applicant(s) and inventor(s) and the claims in Portuguese; Power of Attorney must be filed within 60 days of filing
 - Grace Period: One year before filing in Brazil or the priority date of the application where the disclosure of the invention was made by:

 - Inventor;
 INPI through an official publication of a patent application filed without the consent of the inventor, based on information obtained from him/her as a result of his/her acts; or
 - Third parties, based on information received directly or indirectly from the inventor or as a result of his/her acts



Brazil

- Requests for Examination: Must be filed within 36 months of the PCT filing date
- **Divisional applications:** Voluntary divisionals are permitted; can be filed at any time up until the "end of examination"
 - · "End of examination" occurs when:
 - · Examiner issues a conclusive opinion report regarding patentability

 - (allowance / final rejection report); or

 Thirty days prior to the publication of the conclusive opinion report in the Official Gazette (the time period for when such publication will occur cannot be predicted)
 - whichever occurs last
 - · Divisional of a divisional is not permitted



- · Methods of Treatment claims allowed? No; Swiss-type claims
- Cost (filing and prosecution 100 page application): \$10-80K
- Time line for grant: 9-10 years for mechanical cases; 11-12 years for biotech cases
- · Allowance rate: 20%



Brazil

- - · Submit an amended claims before filing a request for examination
 - Once a request for examination is filed it is impossible to broaden the claims and several restrictions apply
 - · Applicants cannot:
 - · Remove features from the independent claims;
 - Change the category of a claim; or
 Add new independent claims

 - Applicants can:
 Add dependent claims
 Include features in independent and/or dependent claims based on the specification and claims

 - Remove features, words or phrases for the purpose of overcoming lack of clarity autm



- Consider requesting examination for the broadest scope of protection as soon as possible, file divisional applications later to pursue additional
- Prosecution is very slow due to the backlog

 - Consider expedited examination
 PPH programs with U.S., Japan, Europe, Great Britain, Denmark, China and PROSUR (Algentina, Chile, Colombia, Costa Rica, Ecuador, Paraguay, Peru, Uruguay)
 Pharmaceutical products are generally excluded
 Green patents program for applications relating to environmentally friendly inventions

 - Applications related to the diagnosis, prophylaxis and treatment of Acquired Immunodeficiency Syndrome (AIDS), cancer or (pre-defined) neglected diseases, rare diseases and Health products relating to Brazilian National Health System (SUS) program
 - Infringement program if a third party is infringing a patent
 If at least one Applicant is over 60 years of age



Canada

- · What is patentable?
 - · Biological inventions:
 - Patentable
 - Isolated bacteria, cell lines, hybridomas, some related biological materials and their use

 - interials and united by Movel, isolated DNA and proteins Genetically manipulated organisms, genotypically or phenotypically modified hing organisms, for example, genetically modified bacteria, genetically engineered plant cells
 - Not patentable

 - Human beings and methods for their generation
 Plants (including genetically engineered plants) and transgenic animals
 - · Diagnostic methods in flux



Canada

- Business Methods and Computer-related inventions:
 - - Construe the claim using "purposive construction"
 Identify the essential elements of the claim and problem the inventors set out to solve and the solution disclosed

 - to solve and the solution disclosed
 Business Methods: To be patentable must comprise a practical
 application

 Methods which rely solely on the presence of a computer program to
 implement the methodology in order to provide the necessary practical
 application may not be patentable
 Software: If a computer is found to be an essential element (e.g.
 required to solve a practical problem) of a construed claim, the claimed
 subject-matter will generally be statutory
 - Not patentable
 - Computer programs per se, data structures and computer-generated signals



Canada

- · Nuts and bolts
 - Entry deadline: 30 month date (can enter as late as 42 month date with payment of a late fee)
 - Translation required: No (if application is filed in English or French)
 - What is required: Request form; copy of PCT application and any amendments made during PCT procedure and payment of fees; no Power of Attorney needed
 - Grace Period: One year grace period for disclosures made by the Applicant or by another who obtained knowledge, directly or indirectly, from the applicant
 - Extends to filing date; not priority date must file a PCT application or file in Canada by the one-year disclosure bar



Canada

- Requests for Examination: Must be filed 5 years from the filing date of the patent application; the term of requesting examination in a divisional application is 6 months from the presentation of the divisional Divisional applications: While voluntary divisionals are available as a matter of right, generally avoid filing unless there is a lack of unity rejection in order to prevent issues with double patenting
- Methods of Treatment claims allowed? Permitted if not directed to treating a medical condition (e.g., method of conception) or to treating a non-human animal; Swiss-type, Germany style claims (use of x for treating y) and EPC2000 style claims are permitted
- Cost (filing and prosecution 100 page application): \$5-10K
- Time line for grant: 4-6 years
- Allowance rate: 65%



Canada

- - No claim fees exist in Canada; file with as many claims as necessary to protect the invention
 - Be aware of recent Canadian patent law changes will be coming into effect in
 - Entry of National Phase will be strictly 30 months; no more 42-month national phase entry by right; will need to show failure to enter National Phase at 30 months was unintentional and the reasons for the failure will need to satisfy the Commissioner
 Amendment after allowance practice streamlined

 - Americalization and advance practice streamined

 Notice of allowance can withdrawn and prosecution an be re-opened upon payment of a fee
 within four mornits of the date of allowance and before the issue fee is paid

 Shortened prosecution deadlines

 Term for requesting examination will be reduced from 5 years to 4 years and from 6 months to 3 months in divisional applications.

 Responses to Examiner's Reports will be 4 months instead of 6 months (but a two month obstance) or thin will be a smalled). In desiration constructions.

 - Prosecution history may be relevant to claim construction
 Third party rights may arise when a patent application is abandoned and resinstated.



China

- · What is patentable?
 - · Biological inventions:
 - Patentable
 - Isolated pure microbes with industrial use, cell lines, hybridomas and their use
 - Novel, isolated DNA and proteins
 - Genetically manipulated microorganisms, genotypically or phenotypically modified living microorganisms, for example, genetically modified bacteria
 - Not patentable
 - Human beings and methods for their generation
 - Human beings and methods for their generation
 Methods for the diagnosis or treatment of living humans and animals
 If the immediate purpose of a method is to obtain a intermediate result rather than
 obtain a diagnosis result or determine a health condition, the method is patentable
 to the immediate purpose or material.
 - Instruments or apparatus for implementing such methods or substances or materials for use in such methods are patentable
 - Plants and animal varieties (including genetically engineered ones)



China

- · Business Methods and Computer-related inventions:
 - Patentable
 - Business methods: Patentable provided that the claims recite technical features, especially if the features are of a physical nature
 - Computer program related inventions: Patentable provided the claims recites a technical solution
 - Can get claims to a "computer program product" or a "machine-readable medium"
 - Can get claims to a process for resolving a technical problem with reciting specific steps of executing computer programs
 - · Not patentable
 - Business methods and computer programs per se



China

- · Nuts and bolts

 - and bots

 Entry deadline: 30 months (can be extended by two months by paying a fee)

 Translation required: Yes, into Chinese which must be filed within the time limit of national phase entry

 What is required: Request form; copy of PCT application and any amendments made during PCT procedure and payment of fees; Power of Attorney should be filed within two months

 Grace Period: Six months where:
 - Grace Period: Six months where:

 - Invention was first exhibited by the Applicant at an international exhibition sponsored or recognized by the Chinese government
 Invention was first made public by the Applicant at a prescribed academic or technology-related meeting
 Invention was publicly disclosed by a person without authorization



China

- · Requests for Substantive Examination: Must be filed within three years from the priority date
- Divisional applications: Voluntary divisionals can be filed at any of the below times:
 - If the parent application is granted, before or within 2 months from the date of receipt of Notice of Allowance
 - · If the parent application is rejected,
 - Before or within 3 months from the date of receipt of a Rejection Decision
 - During a reexamination procedure (appeal before the Patent Reexamination Board)
 - During the period of appeal against the Reexamination Decision in the Court autm

- Methods of Treatment claims allowed? No; Swiss-type claims
- Cost (filing and prosecution 100 page application): 15-20K
- Time line for grant: 3-5 years
- Allowance rate: Between 40-50%



China

- Tips
 - Include at least some (preliminary) data (proof of effect) in the application as filed to satisfy disclosure requirements
 - Need at least one operative embodiment
 - Claims covering embodiments not disclosed in the specification and that are not conceivable by a person skilled in the art will be rejected as too broad
 - Post-filing data will only be accepted if the technical effect to be verified is deducible from the application as filed
 2017 Amendment to SIPO Guidelines on accepting post-filing data



China

- Enforcement
 - Worked hard to improve the court system; since 2014 implementing changes at a breathtaking pace
 - Specialized IP courts/tribunals exist in 21 big cities across the country, including Beijing, Shanghai and Guangzhou
 - · Hear all first instance patent matters in these regions
 - Judges have IP training and background to facilitate the proceedings
 - Official technology investigator assists judges to ascertain
 - technical issues Beginning in 2019, a newly established IP Tribunal of Supreme People's Court will hear all second instance patent cases nationwide



China

- Misunderstandings about patent litigation in China -Research by Renjun Bian
 - Looked at Chinese Judgments on-line (CJO) from 2014
 - 1,600 cases analyzed
 - IP owners won more than 80% of the time and permanent injunctions were issued by the Chinese courts in more than 90% of the cases
 - Foreign companies enjoyed a slightly higher success rate for both proving infringement and obtaining an injunction compared to their Chinese counterparts



China

- Issues remain
 - · Evidence collection is difficult
 - · Damage awards are low
 - Difficult to obtain compensatory damages; generally statutory damages are awarded
 - Situation is getting better (draft Fourth Amendment to Patent
 - Statutory damages increasing from RMB 1 million to RMB 5 million
 - · Award of punitive damages for serious and intentional infringements



Japan

- · What is patentable?
 - · Biological inventions:
 - Patentable
 - Isolated bacteria, cell lines, hybridomas, some related biological materials and their use
 - · Novel, isolated DNA and proteins
 - Genetically manipulated organisms, genotypically or phenotypically modified living organisms, for example, genetically modified bacteria, plants, animals
 Diagnostic methods for the treatment of humans and animals provided a sample is removed from the body
 - Not patentable
 - Human beings and methods for their generation



Japan

- Business Methods and Computer-related inventions:
 - Patentable
 - Business methods: Patentable if said methods are performed by means of Information Communication Technology (ICT)
 - Software related inventions: Patentable provided that all steps of
 - Hardware that executes each step in the procedure must be explicitly stated in the claims (i.e., a program that makes a processor execute steps A, B and C)
 - · Not patentable
 - · Business methods per se



Japan

- · Nuts and bolts
 - Entry deadline: 30 months (not extendible)
 - Translation required: Yes, into Japanese; can be provided 2 months after entering the National Phase
 - · What is required:
 - Minimum requirements for filing are:

 - Request to Grant a Patent
 Application materials in any language
 - Applicant and Inventor Details
 - No Power of Attorney required



Japan

- Grace Period: 12 months does not apply to a foreign priority application; file a PCT or in Japan directly
 - · Relates to acts, disclosures and exhibitions made by the Applicant or made by a third party against the will of the person having the right to obtain a patent
 - Proof of disclosure should be filed within 30 days of entering the National Phase or if an applicant has made a request for examination before entering the National Phase, the proof should be filed within 30 days from the time when said request was made



Japan

- Requests for Examination: Request for examination must be filed within 3 years of the PCT filling date
 Divisional applications: Voluntary divisionals can be filed at any of the below times:
 - · Before receipt of a first Office Action;
- Before receipt of a first Office Action;
 When replying to an Office Action;
 Within 4 months from the date of the Decision of Rejection; or
 Within 30 days of the date of the Notice of Allowance;
 Methods of Treatment claims allowed? No; Swiss-type claims are allowed (note: methods of treatment of non-human animals are permitted)
 Cost (filling and prosecution 100 page application): \$15-20K
 Time line for receiving a first Office Action: About 11 months from the date of filling a request for examination
 Allowance rate: 71%



Japan

- Tips
 - Including data and/or working examples in the application is extremely important Japan is stricter than U.S. and EP
 Failure to do so will result in the claims being rejected for a lack of enablement

 - enablement
 Can post-filing evidence be submitted? Depends
 If the application does not meet the enablement based on the disclosure at the time of filing, the submission of additional experimental data will not remedy this deficiency
 Additional experimental data may be accepted if it is being used to:
 Demonstrate that the technical effect predicted in the specification would be achievable based on the general knowledge at the time of filing, or
 Provide supportive evidence that a person skilled in the art could obtain the desired experimental results
 Claims must also be commencurate with the actual disclosure
 - Claims must also be commensurate with the actual disclosure



Thank you - Foreign Law Firms













Questions? —	
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