Patent Cooperation Treaty:
Evaluating the Benefits and Risks,
Obtaining International Patent Protection
Navigating the PCT, Priority, Selection of International Authorities, PCT Search and Examination, and More

THURSDAY, SEPTEMBER 14, 2017
1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today’s faculty features:


Jens Viktor Nørgaard, Partner, Head of Biotechnology & Plant Sciences, HØIBERG, Denmark

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Jens Viktor Nørgaard, HØIBERG
Rebecca McNeill, McNeill Baur PLLC

September 14, 2017
Outline

• Advantages and disadvantages of using PCT
• Writing one application
• Receiving office consideration
• International Searching Authority consideration
• Priority applications
• Making changes
• Unity of Invention
• Active prosecution in the PCT phase
• National stage entry
• Recent changes
• Getting help in your PCT application
Advantages and disadvantages of using the PCT
Advantages and Disadvantages

• Should you always use the PCT route?

  – Cons
    • Increases your total cost
    • Creates examination delays

  – Pros
    • Defers significant expenses
    • Allows you to postpone decisions
    • Streamlines formalities initially
    • Provides search report and written opinion
Advantages and Disadvantages

• In most instances, pursue PCT countries through PCT routes
  – Consider filing directly via Paris Convention when:
    • Country choice is certain
    • Total cost is more important than timing of cost
    • Want to expedite grant

• Be mindful of choice to file a PCT application
  – Don’t be a robot!
Writing one application
Writing One Application

• When you prepare your priority application (often US provisional) and when you update for the PCT stage, keep in mind you are writing for worldwide prosecution
US Considerations

• Expect many in our audience today are US practitioners
  – Take all the steps you usually do for a US application
    • Keep in mind differences in country law
  – Adequate written description and enablement support for broad, intermediate, and narrow embodiments
US Considerations

• Patentable subject matter differs between countries
  • Patent eligibility under 35 USC § 101
    – Natural products
    – Laws of nature and abstract ideas
      » Test and treat vs. diagnosis
    – Support both US claims and other countries
EPO Considerations

• **Priority**

  – **Challenge**
  • Same applicant (inventor vs applicant)
  • Added matter?
  • Intervening publications

  – **Solution**
  • File the priority application in the name of the applicant (assignee)
  • File a complete application
EPO Considerations

- **Amendments**
  - **Challenge**
    - Directly and unambiguously derivable
    - No cherry picking
  - **Solution**
    - Use multiple dependent claims or items/embodiments
    - Single out preferred embodiments
    - Describe what a particular feature does
    - Describe your invention
EPO Considerations

• Inventive step

  – Challenge
    • Technical problem solved by the invention
    • Technical effect of features

  – Solution
    • Tell the story – sell the invention, help the examiner understanding how brilliant the invention is
    • Add the technical effect of features
Other countries/regions

– **Claims**
  - India and China charge claims fees based on number of PCT claims
  - Prepare list of items as part of description to reduce claims fees

– **Enablement/support**
  - China, South Korea – data needed in biotech/chemistry

– **Exceptions**
  - Medical use/method of treatment not patentable in India
Receiving Office selection
Selection of the right office
Receiving Office Selection

• In most instances, US attorneys can file PCT applications through the US Receiving Office (US RO)
  – File via EFS-web

• But must have at least one applicant who is a resident or national of the US in order to use the US RO
Receiving Office Selection

• What if you do not have a US applicant
  – Foreign-domicile assignee
  – All foreign inventors (residence and citizenship)
  – Cannot use the US RO

• Some patent attorneys name themselves as an applicant or an inventor?
Receiving Office Selection

• If you are not entitled to use the US RO, can still file via EFS web in an emergency
  – US RO will transfer the application to IB so long as there is an applicant who is a resident or national of a PCT-contracting state
  – Will receive filing date from US RO filing
    • Avoid the loss of filing date when US RO is not competent to act
Receiving Office Selection

• Can work with foreign counsel for filing of PCT application
  – Multi-jurisdictional company
    • Rights assigned to the country X subsidiary
    • Inventors in country X
    • Coordinate with firm in country X to file PCT
    • REQUIRES advanced planning
Filing in RO/IB

• Can file in WIPO using the International Bureau as the Receiving Office (RO/IB)
  – Must obtain a foreign filing license (FFL) before transmission to IB
    • Expedited FFL
    • Can submit via EFS-Web
    • 3-day turn around time
    • Plan ahead!
Filing in RO/IB

• How to file:
  – electronically via ePCT or PCT-SAFE
  – fax to +41 22 910 06 10
    • Alternative number 41 22 338 70 60
    • Must provide original within 14 days
  – by mail
  – hand-delivery to WIPO headquarters
Filing in RO/IB

• Can file in WIPO using the International Bureau as the Receiving Office (RO/IB)
  – Filing date=the day WIPO receives appln.
    • Irrespective of transmission method
    • Fax: last page must be received before 12:00 midnight Geneva time!
International Searching Authority
Selection of the right office
Competent ISAs for US applicants

- Australia
- EPO
- Israel
- Japan
- Korea
- Russia
- Singapore
- USPTO
# ISA Costs

<table>
<thead>
<tr>
<th>ISA</th>
<th>Search Fee - USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>AU</td>
<td>1,688</td>
</tr>
<tr>
<td>EP</td>
<td>1,992</td>
</tr>
<tr>
<td>IL</td>
<td>963</td>
</tr>
<tr>
<td>JP</td>
<td>1,372</td>
</tr>
<tr>
<td>KR</td>
<td>1,114</td>
</tr>
<tr>
<td>RU</td>
<td>482</td>
</tr>
<tr>
<td>SG</td>
<td>1,552</td>
</tr>
<tr>
<td>US</td>
<td>2,080 (large entity)</td>
</tr>
</tbody>
</table>
## Cumulative Search fees EPO

<table>
<thead>
<tr>
<th>ISA</th>
<th>Search Fee</th>
<th>Supplementary EP fee</th>
<th>Total - USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>AU</td>
<td>1,688</td>
<td>1,310</td>
<td>2,998</td>
</tr>
<tr>
<td>EP</td>
<td>1,992</td>
<td>0</td>
<td>1,992</td>
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<tr>
<td>IL</td>
<td>963</td>
<td>1,530 (1300 EUR)</td>
<td>2,493</td>
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<tr>
<td>JP</td>
<td>1,372</td>
<td>1,310</td>
<td>2,682</td>
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<tr>
<td>KR</td>
<td>1,114</td>
<td>1,310</td>
<td>2,424</td>
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<tr>
<td>RU</td>
<td>482</td>
<td>1,310</td>
<td>1,792</td>
</tr>
<tr>
<td>SG</td>
<td>1,552</td>
<td>1,310</td>
<td>2,862</td>
</tr>
<tr>
<td>US</td>
<td>2,080 (large entity)</td>
<td>1,310</td>
<td>3,390 (large entity) 2,350 (small entity)</td>
</tr>
</tbody>
</table>
ISA Factors to Consider

• Purpose of PCT phase
  – Postponing costs
  – Certainty about patentability

• High quality search
  – Filing demand

• Lowest possible price
ISA Exceptions

• Searched subject matter
  – Business methods
  – Method of treatment (EPO searches method of treatment as second medical use claims)
  – Computer programs
Supplementary International Search

• One or more supplementary international searches (SIS) may be requested by applicant from participating ISAs

• Time limit is 19 months from priority date (as of 1 July 2017 extended to 22 months)(R. 45bis(a))

• Supplementary search fee and handling fee payable to IB
Supplementary Search

- Austria (in German)
- EPO
- Finland
- Russia
- Sweden
- Singapore
- Turkey
- Ukraine
- Nordic Patent Institute
- Visegrad Patent Institute
Supplementary Search

• When to use Supplementary Search?
Priority applications
Priority Documents

• Easy access via DAS system
• File PCT application in office of first filing for ease
Correction of Priority Claim

• Can be done vis-a-vis the RO before 16 months from priority date/ 4 months from date of filing
Restoration of Priority Right

• PCT Rules 26bis.3 and 49ter.2
• File request with RO before 16 months from priority date
• Reasons:
  – Unintentional or
  – Despite all due care
Restoration of Priority Right

• With few exceptions for all Receiving Offices and as designated states

• If PCT restoration is under “unintentional” standard, priority must be restored at designated offices that apply “all due care”.

HØIBERG
European patent & trademark attorneys

MB MCNEILL|BAUR
Intellectual Property Law
All Due Care

• EPO and most EP contracting states
• Japan, Israel
No Effect of Restoration

- Reservations under Rule 26bis3(j):

  - BE, BR, CO, CU, CZ, DE, DZ, GR, ID, IN, IT, KR, NO, PH
Restoration of Priority Right

• Beware of EPO’s very high standard for “all due care.”

• Normally requires at least one cross check of due dates, one by authorised attorney and one by experienced paralegal/assistant
Making changes
Recording of Changes

• 92bis.1 *Recording of Changes by the International Bureau*

• Changes in:
  – (i) Person, name, residence, nationality or address of the applicant,
  – (ii) Person, name or address of the agent, the common representative or the inventor.

• Deadline: up till 30 months from the priority date.
Incorporation by Reference

• Applies automatically for all applications filed with official PCT request

• Incorporate subject-matter from priority document

• Two months from filing or invitation from RO
Incorporation by Reference

- Reservations by designated offices:

- CN, CU, CZ, DE, ID, KR, MX, TR
Obvious mistakes

• Correction of an obvious mistake in the request shall be authorised by the Receiving Office (R.91.1(b)(i)).

• Correction of an obvious mistake in description, claims or drawings shall be authorised by ISA or IPEA (R. 91.1(b)(ii)(iii))
Obvious mistakes

- For correction of obvious mistakes in description, claims, drawings:
  - Both the mistake and the rectification of that mistake have to be obvious to the competent authority.
Obvious mistakes

• The competent authority shall promptly decide whether to authorise the requested rectification and notify applicant and IB of its decision (R. 91.3(a))

• Rectification shall take effect from international filing date or the date the document containing the mistake was filed (R. 91.2(c))

• A designated office may disregard a rectification of an obvious error if the designated office would not have authorised the rectification, however applicant must be given the opportunity to make observations (R. 91.3(f))
Chaning Priority Claim

• Correction or addition of priority claim under Rule 26bis

• Time-limit: 16 months from earliest priority date
Making Amendments

- Art 19 amendments
- Until 16 months from priority date or
- 2 months from the ISR

- Filed with the IB – not the ISA or RO
Art 19 Amendments

- No arguments needed
- Statement may be filed
- Basis for amendments required

- Further possibilities for amendment during International Preliminary Examination
Unity of Invention
Unity

• The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (“requirement of unity of invention”) (R. 13.1 PCT)

• If ISA considers that the international application does not comply with the requirements of unity, it shall invite the applicant to pay additional fees. (Art. 17(3)(A) and rule 40.1.)
Unity

• The amount of the additional fee is determined by the ISA (R. 40.2(a)) and shall be payable directly to ISA (R. 40.2(b)).

• EPO as ISA requires an additional international search fee for each additional invention (R. 158(1) EPC)
Unity

• The applicant has the following options:
  
  – A: pay the fee(s)
  
  – B: pay the fee under protest (rule 40.2(c)). ISA may request payment of a protest fee (rule 40.2(e)).
  
  – C: not pay
Unity

• National law may provide that those parts of the international application which have consequently not been searched shall be considered withdrawn unless a special fee is paid by the applicant (Art.: 17(3)(b) PCT)

• EPO
# Restriction/Unity

<table>
<thead>
<tr>
<th>Claim Types</th>
<th>Compound Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compounds</td>
<td>A</td>
</tr>
<tr>
<td>Method of manufacture</td>
<td></td>
</tr>
<tr>
<td>Method of treatment</td>
<td></td>
</tr>
<tr>
<td>Formulation</td>
<td></td>
</tr>
<tr>
<td>Screening assay</td>
<td></td>
</tr>
</tbody>
</table>

**Primary US Division**

**EPO Division**
Unity

- Same or corresponding technical features which together provide an inventive contribution over the state of the art ("special technical features")

- **Examples of special technical features:**
  - Common structure
  - Same essential structural element (intermediate and final products)
  - A significant structural element (Markush claims)
  - Common function
  - Common manufacturing steps

- **Same invention:**
  - Apparatus and product made by apparatus
  - Method of manufacturing, product, and method of use
Unity

– No division among: protein, DNA, cell, vector, antibody, method of expressing, medical use, screening assays

– Different scope for different claim categories possible
  – Narrow product claim
  – Broad use-claim
  – Broad manufacturing claim
Unity

• Objections raised at search stage

• No possibility to amend claims to overcome prior art to provide a special technical feature

• Left at the mercy of the examiner - often they divide claims more or less arbitrarily into different inventions

• Not possible to claim unsearched subject matter at a later stage of prosecution
EPO – Regional Phase

• ISA≠EPO
  • If claims filed upon EP entry lack unity =>
    – EPO searches the invention first mentioned
    – Issues an invitation to pay additional search fees

• ISA=EPO
  • If claims filed upon EP entry lack unity =>
    – EPO issues an invitation to pay additional search fees
    – EP search fee: 1,285.00 €
    – International search fee: 1,875.00 €
Active Prosecution in the PCT phase
PCT for Active Prosecution?

• What are your goals for using the PCT
  – Buying time to make decisions?
  – Delaying costs?
  – Don’t know—I just file PCT?

• Can gain advantages by using PCT phase substantively
Using Your Search

• Use the search to gauge the prior art
  – Did client accurately represent the state of the prior art?
  – Did the PCT Examiner uncover significant prior art?
  – Has your viewpoint on patentability changed?
Using Your Search

• Does the search or written opinion change your national stage strategy?
  – Reconsider costly national stage entry if problematic art identified
  – Let the client know about potential weaknesses in patentability
    • Better now than later...
  – Client can make informed decisions
Continuing PCT Examination

• What do you do when you disagree with the Examiner?
  – Can continue examination process in the PCT phase
  – Enter Chapter II: International Preliminary Examination

• Demand fees in US: $206 handling fee and $600-$760 preliminary examination fee for the USPTO as the International Preliminary Examining Authority (IPEA), depending on whether USPTO was ISA in Chapter I
Chapter I vs. Chapter II

The PCT system
Chapter I vs. Chapter II

• Historically, Chapter I terminated at 20 months and Chapter II was the only way to file national stage applications at 30+ months
  – Nearly all countries have accepted extension of Chapter I
  – Only a few outliers
    • Reason direct national stage entry due in Luxembourg, Tanzania, and Uganda are due at 20 months
Chapter I vs. Chapter II

• Now both Chapter I and Chapter II extend to 30-month national stage entry

  – Chapter II
  
  • Allows for continued substantive prosecution
  
  • Requires Demand for International Preliminary Examination
    
    – Due *later of* 3 months from date of transmittal of the international search report and written opinion –or– 22 months from the priority date
Chapter I vs. Chapter II

• Consider filing a demand when you want to:
  – Amend the claims
  – Argue for patentability
  – Obtain a second substantive communication from the PCT Examiner
  • PCT Examiner will maintain original position unless you amend or argue
  • In some jurisdictions (for example EP), the Examiner will perform a ”top-up” search in Chapter II
When to Amend/Argue

- Obtaining a favorable search report yields benefits in national stage
  - Opens up PCT patent prosecution highway (PPH)
  - In some countries, Examiners defer to PCT
    - May still search again, but sets a positive tone
  - Can show to potential partners and investors
When to Amend/Argue

• Do you have amendment or argument that will win on first try?
  – Did Examiner misunderstand aspect of prior art or invention
  – Is the reference, in fact, prior art?
    • Check dates
  – Is there an easy amendment that will negate the rejection
  – Did you miss window for Article 19 Amendments
Amendments and Arguments

• Article 34 provides for opportunities to amend the claims, specification, and drawings
  – Opportunity to amend the specification and drawings (not permitted in Article 19)
  – No new matter
Risks of Chapter II

• Putting statements on the record at odds with later strategy

• Examiner bolsters arguments against patentability

• Identification of new art
  – Examiner will likely perform a “top-up” search to identify newly published prior art
    • EPO, for example, maintains this “adds value”
National stage entry
National Stage Entry

• When is my national stage application due?
  – 21 months?
  – 30 or 31 months
  – 32 or 34 months

• All calculated from priority date
  – If you file a provisional:
    only 18 months from PCT filing
National Stage Entry

• **20- or 21-month countries**
  – Can pursue all through regional applications
    • Luxembourg, Tanzania, Uganda
  – **30- or 31-month countries**
    • Most countries
  – **32+-month countries**
    • Some countries extend for $$$ (Canada, China, Philippines, Turkey)
    • Bosnia and Herzegovina 34 months
National Stage Entry

- 20- or 21-month countries not relevant for nearly all situations
- Treat all 30- and 31-month countries as 30-month countries
  - Don’t make a mistake!
  - Don’t rely on your memory
  - Careless errors happen
  - Pursue China and Canada with 30-month countries
National Stage Entry

• Where to enter the national stage?
  – Major markets
    • Now
    • Within the next 18.5 years
  – Locations of competitors
  – Importance of application
    • A, B, and C tiers
  – Financial resources
National Stage Entry

• Where to enter the national stage?
  – Based on need
    • Solving problem in that country
      – Mining device
    • Disease incidence
      – Lung cancer: look at incidence of cancer + smoking rates’
  – Request feedback on patentable subject matter from foreign counsel
    • Methods of treatment
      – (2+ drugs, 1 method)
National Stage Entry into the US

• Have you filed a US application yet?
• Some applicants defer US until the PCT stage
  – Delay costs
  – Perhaps a University waiting for a licensee
Two Routes into the US

• Two routes into the US from the PCT
  – National stage application under 35 USC § 371
  – Continuation from the PCT under 35 USC § 120
    • Bypass continuation
    • Also CIP or DIV

• Different filing requirements and advantages
## Two Routes into the US

<table>
<thead>
<tr>
<th>Bypass Continuation</th>
<th>National Stage Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can pay fees at missing parts</td>
<td><strong>Must</strong> pay fees upon filing</td>
</tr>
<tr>
<td><strong>Must</strong> file application copy</td>
<td>If PCT appln. filed in USRO or if IB/308 issued, do not need to file copy of application</td>
</tr>
<tr>
<td>Requires certified priority documents</td>
<td>No priority documents for filing</td>
</tr>
<tr>
<td>Examined under US restriction practice</td>
<td>Unity of Invention practice</td>
</tr>
<tr>
<td>Can file Track I application</td>
<td>Cannot file Track I application <em>(potentially expensive mistake!)</em></td>
</tr>
<tr>
<td><strong>Must</strong> claim priority to PCT and any other priority applications</td>
<td>Designate as national stage</td>
</tr>
</tbody>
</table>
National Stage Entry

• Make sure upon entry to the US that you are filing the right type of application
  – Talk to your support staff
  – Check paperwork carefully to match your intent
Patent Prosecution Highway

• Can you use the PCT-PPH?
  – Can rely on
    • Written Opinion of the International Searching Authority
    • Written Opinion of the International Preliminary Examining Authority
    • International Preliminary Examination Report in some instances
Patent Prosecution Highway

• Can you use the PCT-PPH?
  – Country performing the work and national stage entry country must have a PCT-PPH agreement
    • US has PCT-PPH agreements with Austria, Australia, Canada, China, EPO, Finland, Israel, Japan, Korea, Russia, Sweden, and Nordic Patent Institute
Recent changes
Sending Data to IB

- Recent changes include a requirement for designated offices to timely send national phase entry and related data to the IB (PCT Rules 86 and 95)
  - Will increase accuracy of national stage entry information
Transmission of Search Results

• Changes require receiving offices to transmit earlier search and/or classification results to the International Searching Authority (PCT Rules 12bis, 23bis, and 41)
  – Promotes efficiency and reduces “rework”
Earlier Search

• Applicant may request that ISA takes earlier international, international-type or national search into account (R. 4.12)

• Applicant must submit copy of the results of the earlier search at filing (R. 12bis.1)
Earlier Search

• If earlier search is prepared by rO it may be requested in the Request that rO submits the copy – subject to fee
• As of 1 July 2017 rO shall forward result of earlier search (new PCT Rule 23bis.2)
• If earlier search is prepared by ISA no copy is required (R. 12bis.1(e))
• Copy of earlier application, translations and copies of cited documents may be requested
Earlier Search

- Where the earlier search was carried out by the same Office that now acts as ISA, the earlier search must be taken into account (R. 41.1(i))

- Where the earlier search was carried out by any other Office, the ISA may take the earlier search into account (R. 41.1(ii))
Earlier Search

• EPO as ISA refunds search fee in full or in part if EPO searched the priority application

• Search with Written Opinion
  – 100%
  – 25%

• Search without Written Opinion
  – 70%
  – 17.5%
EPO Add On

PCT Direct
• EP priority with search report/opinion
• File PCT with EPO as ISA
• File arguments with PCT, indicate amendments in marked-up version
• No official fee
• Increases chance of positive Written Opinion
• Reduces need for demand
PCT Direct

Filing EP priority
Prepare response and amendments
Considered by ISA
Search fee returned
EESR Search report and opinion
Filing PCT application with arguments
ISR-WO
National entry
PCT Direct, US Version

- Filing US provisional
- File EP application
- Prepare response and amendments
- Considered by ISA
- Foreign filing license
- EESR Search report and opinion
- Filing PCT application with arguments
- ISR-WO
Supplementary Search

• Recent changes also extended the deadline for requesting a supplementary international search from 19 to 22 months
  – Rarely request supplementary search
Getting help in your PCT application
Getting Help

• USPTO
  – PCT Helpdesk
    • 571-272-4300
  – PCT Legal Office
    • 571-273-0459
  – PCT applications, international, and national phase
    • 703-305-3165
Getting Help

• General or Legal Questions
  – +41 22 338 8338

• Filing a PCT application using the International Bureau as the RO
  – +41 22 338 9222
Getting Help

• WIPO PCT Legal Division
  – pct.legal@wipo.int
  – Matthias Reischle
    • Deputy Director, PCT Legal Division
    • +41 22 338 96 27
    • matthias.reischle@wipo.int
Getting Help

• WIPO PCT Legal Division
  – Mr. Reischle’s “Learn the PCT” YouTube Videos!
  • 29 informative and friendly episodes
Getting Help

- Technical problems
  - ePCT, PCT-SAFE
  - +41 22 338 9523
Thank You and Questions

Jens Viktor Nørgaard

jvn@hoiberg.com
011 45 3332 0337

Rebecca M. McNeill

rebecca.mcneill@mcneillbaur.com
617.489.0002