Panelists

Marco Aleman, Director, Patent Law Division, WIPO

Yansheng YU, Patent Attorney, China Patent & Trademark Agent (U.S.A.), Ltd.

Arvie Anderson, Sr. Director, Asst. Gen’l Patent Counsel, Eli Lilly and Company

Nick Bassil, Partner, Kilburn & Strode

Moderated by: Paula Davis, Pfizer Inc.
33rd Annual Intellectual Property Law Conference
Coming Together: Worlds Apart

Marco M. ALEMAN
Director, Patent Law Division, WIPO

Arlington, Virginia, April 18 to 20, 2018
Recent developments in international patent law harmonization

1. What the contribution of multilateral treaties administered by WIPO has been
2. The current negotiations at the SCP (WIPO). The multilateralism “in crisis” and the hope for faster progress elsewhere (bilateral and plurilateral negotiations)
Contribution of multilateral treaties administered by WIPO on Patents

- The Paris Convention (1883)
  - The PCT (1978)
  - The Budapest Treaty (1979)
  - The PLT (2000)
Administration and Promotion of Treaties

The PCT now has 152 Contracting States

Paris Convention now has 176 Contracting Parties
Administration and Promotion of Treaties

Budapest Treaty now has 80 Contracting Parties

Patent Law Treaty now has 39 Contracting Parties
## Administration and Promotion of Treaties

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<tr>
<td><strong>IP Protection</strong></td>
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<tr>
<td>Budapest Treaty (1977)</td>
<td>Regulates the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.</td>
<td>72</td>
<td>80</td>
<td>+11.11%</td>
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<td>Paris Convention (1883):</td>
<td>Applies to industrial property in the widest sense; covering all major IP areas.</td>
<td>173</td>
<td>177</td>
<td>+2.31%</td>
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<td>Patent Law Treaty (2000)</td>
<td>Harmonization and streamlining of formal procedures with respect to national and regional patent applications and patents and making such procedures more user friendly.</td>
<td>22</td>
<td>39</td>
<td>+77.27%</td>
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Patents applications worldwide (2016)

**Applications**

Note: World totals are WIPO estimates using data covering 154 patent offices. These totals include applications filed directly with national and regional offices and applications entering offices through the Patent Cooperation Treaty national phase (where applicable).


**Trend in non-resident applications by filing route**

**PCT NPE SHARE (%)**

**Application year**

Note: A patent office may receive patent applications filed either directly with the office (known as the “Paris route”) or through the Patent Cooperation Treaty System (Patent Cooperation Treaty national phase entries).

Figure 4: Patenting activity has been geographically concentrated

Share of first patent filings in world total

Notes: This figure is a summary of figures 2.3, 2.5, 2.8, 3.2, 3.7 and 3.12, covering the same time periods as the ones shown in those figures. Note that the bars do not exactly sum up to 100 percent, reflecting unknown origins in less than 1 percent of first patent filings.

Source: WIPO based on PATSTAT database (see technical notes).
The Standing Committee on the Law of Patents (SCP)

- Formality and Procedural aspects: the PLT
- Discussion on substantive patent law issues
- Current Agenda
1998: SCP established

2000: Adoption of PLT (!). Start of SPLT discussions

2005: PLT enters into force

2006: Decision to stop SPLT discussions

Deadlock between 2006-2008

2010-2011: Agreement on five issues for future work

2010-2011: Agreement on five issues for future work
The Patent Law Treaty

39 Members (the last to join was Belarus)

In the process of implementation are Belgium, Canada and the Republic of Korea

Important work ahead (promotion and assistance to MSs in its implementation)
PLT Contributions for applicants and representatives

Reliance on a familiar set of patent formalities in all countries party to the PLT
- easier access to foreign patent systems
- enhanced legal certainty
- cost reductions

Reduced risk that rights would be lost because of failure to comply with formalities
- offices would be required to notify applicants of formal mistakes and give them an opportunity to correct those mistakes
- relief and re-instatement of rights in the case of missing certain time limits

Others
- exceptions from mandatory representation
- possibility to obtain a filing date, even if the description is filed in a foreign language
SCP current agenda

- five issues for future work
  (i) exceptions and limitations  
  (ii) quality of patents  
  (iii) patents and health  
  (iv) transfer of technology  
  (v) client-patent attorney privilege

- SCP/28: July 9 to 12, 2018
In 2010 Brazil proposed to carry out three phases of work:
(1) exchange of information
(2) relevance of exceptions and limitations to development
(3) non-exhaustive, non-binding Manual

African Group, Asian Group, GRULAC, Russia, China and others

Group of Central European and Baltic States, EU, Group B and others


MOST RESPONSES STATED:

- the legal framework of the exceptions is adequate to meet the objectives sought
- no challenges in relation to the practical implementation of the exceptions
### Questionnaire on Exceptions and Limitations to Patent Rights

Table and links to the replies received from member states and regional offices to the SCP.

- Questionnaire [PDF](http://www.wipo.int/export/sites/www/scp/en/exceptions/submissions/usa.pdf)
Quality of Patents

Quality-related aspects of the System:

- Search and examination
- Third party observation
- Opposition mechanisms
- Practical guidelines & training programs for patent office employees
- Codes of Conduct for patent applicants
- Quality Control
- Quality Management Systems (QMS)
Quality of Patents. Work

**Responses to the Questionnaire relating to the Quality of Patents**

**Submissions from WIPO member states**

<table>
<thead>
<tr>
<th>Member state</th>
<th>English</th>
<th>French</th>
<th>Spanish</th>
<th>Arabic</th>
<th>Chinese</th>
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Quality of Patents. Arguments

Quality of patents is a question of national law that refers to the ability of patent offices to apply their domestic patent laws, thus patentability criteria might be applied differently in jurisdictions in accordance with national priorities and policy objectives.

The proposed initiatives would result in harmonization of practices in the field of patent law, which would be prejudicial to the provisions of flexibility in national legislation.

Support the proposals or certain elements in them.

Common understanding of the definition of “quality of patents” necessary before any work.

Argentina, India

African Group, Algeria, Asian Group, Brazil, Chile, China, DAG, Dominican Republic, Egypt, GRULAC, India, Iran, LDCs

Australia, Canada, CEBS Group, Colombia, Cuba, Denmark, Ecuador, EU, Group B, Paraguay, Korea, Russia, Spain, UK, US
Patents and Health

Main Issues:
- Patentable subject-matter
- Patentability Criteria
- Scope of Protection
- Ethical implications
- Links Research - IP
- Impact of IP on R&D
- Impact on Public Health
Transfer of Technology

- The Committee shall further study patent-related impediments to ToT
- Sufficiency of disclosure
- Compilation of voluntary licenses
- Compilation of information on national/regional regulations, guidelines, practices and jurisprudence regarding voluntary licenses

Patent Law Provisions that contribute with ToT
Confidentiality of Communications

**What should be covered by the privilege?**

- Communications at all stages of the procedure
- Communications w. non-lawyer advisors
- Communications w. foreign IP advisors

**COMMON LAW:**
- Attorney-Client Privilege

**CIVIL LAW:**
- Professional Secrecy Obligation

**Who should benefit?**

- Non-lawyer IP advisors
- Lawyers giving non-legal IP advice
- Registered/qualified IP advisors
- In-house advisors

Protection & advice are increasingly sought in many jurisdictions – more litigation in various jurisdictions - variations in jurisdictions lead to uncertainty and penalize innovative companies seeking or litigating rights internationally.
Client-Patent Attorney Privilege

(i) Elaboration of non-binding minimum standards (a voluntary guide for national authorities) (CH, CEBS)
(ii) A dedicated web page; a seminar with patent advisors and clients (Group B)
(iii) Concerns about limiting disclosure of evidence and harmonization
(iv) Doubts about further discussions in the SCP (a matter of law of evidence - national issue)

**STRENGTHS**
- The broad mandate
- Flexibility in the choice of agenda
- Multilateral Member States’ forum with IGOs and NGOs
- Permanent Committee/Permanent Secretariat with neutrality and expertise

**WEAKNESSES**
- The broad mandate (Political priorities not aligned, political divide and mistrust among MSs, lack of focused or text-based discussions)
- Passive participation of some MSs
- Consensus among divergent views required

**OPPORTUNITIES**
- More developing countries have started to participate in the patent system
- Political incentives to maintain WIPO permanent Committees
- No similar multilateral forum elsewhere

**THREATS**
- The SCP could become irrelevant (progress in other norm setting fora among like-minded countries (ex. Group B+))
- some countries do not find benefits in the SCP discussions (e.g., negative agenda)
MANY THANKS
marco.aleman@wipo.int
Recent Development of Chinese Patent Practice

China Patent Agent (H.K.) Ltd.
April 2018
Prioritized Examination

- Came into effect from August 1, 2017
- Remedy for domestic applicants
  - Chinese local corporations
  - Chinese subsidiaries of foreign corporations
- Applicable to
  - Substantive examination for inventions
  - Preliminary examination for designs and UMs
  - All reexaminations
  - All invalidations
Prioritized Examination - Continued

How fast

For Invention

- Substantive examination within 1 year (regular 2-3 years)
- OA1 in 45 days after grant of prioritized exam (response in 2 months)

For UMs and Designs

- Issuance : 2 months (avg. 8-12 months)
- Reexamination : 7 months (avg. 12 months)
- Invalidation : 4-5 months (avg. 6 months)
Prioritized Examination - Continued

➢ For what technologies

➢ Technology being implemented
  ➢ by Applicants (ongoing or ready to)
  ➢ by others (ongoing)

➢ Applications first filed in China, when foreign filings ensure

➢ Government-promoted Tech, including
Prioritized Examination - Continued

- For what technologies
  - Rapidly Developing Tech, including
    - Internet,
    - Big data,
    - Cloud computing, etc.
  - Industries promoted by government (province and city level)
  - Public or state interest
Prioritized Examination - Continued

Tips

- No voluntary amendments under Rule 51
- No supplementary evidence or grounds from Invalidation petitioner
- No extensions in reexamination
- No claim amendments during invalidation* (*deleting claims Okay)
Amendments to patent documents

Subject to the above principles of amendments, the specific manners of amendments are generally limited to deletion of a claim, combination of claims, deletion of a technical solution, further limitation for a claim, and correction of an obvious error.

“further limitation for a claim” means incorporation into the claim one or more technical features recited in other claims so as to narrow the scope of protection.

*Last claim comprising all features from description could be a good practice
(2) Except the cases described above in point (1), if a claim in its whole contents contains not only matter of rule or method for mental activities but also technical features, then the claim, viewed as a whole, is not a rule or method for mental activities, and shall not be excluded from patentability under Article 25.

- No Art. 25 rejection if technical features are involved
- Subject to rejection on inventiveness if the differentiating features are not technical features
Post-Filing Data

- Revision of Examination Guidelines last April
  - Whether or not the description is sufficiently disclosed is judged on the basis of the disclosure contained in the initial description and claims. With respect to experimental data submitted after the date of filing, they should be examined by the examiner. The technical effect proved by the supplementary experimental data should be one that can be derived by a person skilled in the art from the disclosure of the patent application.
  - Post-filing data should be considered by examiners.
  - In practice, SIPO’s threshold is still very high.
Post-Filing Data - Continued

- Original data for proving technical effect of the invention is always required to be in the original application in order for the examiner to consider supplementary data.
  - If there is original data, the supplementary data should be considered and can be used to prove inventive step of the invention;
  - If there is no original data, examiners always refuse to consider any supplementary data.

- Beijing High Court and Supreme Court believe SIPO’s practice on this matter too conservative and rigid but have never reversed any decision made by PRB between 2014 and 2017.
### Post-Filing Data - Continued

The result of our search for the cases in last few years

<table>
<thead>
<tr>
<th>Effect to be proved by Supplementary Data</th>
<th>Relevant data to the Effect</th>
<th>SIPO (PRB)</th>
<th>Courts</th>
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Administrative Enforcement

- Administrative/Judicial dual tracks on patent enforcement in China
- In comparison to judicial track, administrative enforcement is faster and cheaper
- Injunction is available but no damage
- SIPO is proposing to strengthen patent enforcement power for patent administrative authorities in the Fourth Amendments to the Patent Law.
- Local patent administrative authorities are very active and aggressive in these years.
The Patentee has the burden for collecting evidence of infringement and damages

Supreme Court has reduced the burden for collecting evidence of damages in its interpretation of 2016

If it is hard to determine the loss by the patentee and the patentee has provided preliminary evidence to prove the profits gained by the infringer, while accounting or infringing evidence is mainly controlled by the infringer, the courts may order the infringer to provide the evidence; if the infringer refuses to do so without justifiable reasons, or provides false ones, the courts may determine the profits according to the claims and evidence provided by the patentee.

See the following Huawei vs. Samsung case
If the patent being infringed is a method for making a new product, the burden of proof will shift to the defendant.

When determining direct and contributory infringement in the recent *Iwncomm vs. Sony* case,

- The courts deduced that since the chips used in *Sony*’s cell phones has the claimed WAPI function, *Sony* should have the knowledge of patent infringement by selling them, and
- *Sony* must have tested all models of its cell phones designed and manufactured.
- *Sony* was asked first to prove substantial non-infringing use of the WAPI functional module of a cell phone.
The damages claimed for patent infringement should be determined based on the loss by the patentee, the profit gained by the infringer, the license royalty or statutory damages.

SIPO already increased statutory damages to up to $158,700 and is proposing double and triple damages in the Fourth Amendments to the Patent Law.

As the burden for collection of evidence on damages has reduced, the courts granted a lot of high damage cases in recent years.

See *Huawei vs. Samsung* and *Iwncomm vs. Sony*.
Damages - Continued

For invention patents (2015-2016)

- Three IP Courts
- Other courts

Average damages

www.cpahtd.com
Huawei v. Samsung, Case No. 725, Quanzhou (2016)

The 1st instance judgement issued on March 29, 2017

Awarded damages of RMB 80,000,000 (around USD 11 million)

On Sales Volume

IDC data shows the sales of USD 12.7 billion

Defendant questioned the authenticity of IDC data, but did not provide counter evidence

IDC data of USD 12.7 billion applies
On Profit

- 2015 Financial Report of Samsung showed the profit rate 13.2%
- The public data of Ministry of Industry and Information Technology (MIIT) showed the average profit data 3.2% for domestic cellphones

Court’s Holding:

- The profit shall be between 3.2%~13.2%
- Hence the damage shall be between (USD 12.7 billion*3.2%~USD 12.7 billion*13.2%)*6.5 = RMB 2.6 billion~10.9 billion
- The claimed damages RMB 80 million is fully supported

Fujian High Court upheld the decision during appeal
The First SEP Injunction in China

Claim 1 of China patent No. ZL02139508.X

1. A method for secure access and data encryption in WLAN, comprising:
   - Step 1, Mobile Terminal MT sending MT certificate to Access Point AP to request certified access;
   - Step 2, Access Point AP sending the MT cert. to Authentication Server AS and requesting authentication;
   - Step 3, Authentication Server AS authenticating AP and MT;
   - Step 4, if step 3 succeeds, AS sending the results for AP and MT to AP and proceeding to step 5; otherwise, AP rejecting access of MT;
   - Step 5, AP returning the results to MT;
   - Step 6, MT judging the result for AP if it passes, and if yes it proceeding to step 7, otherwise MT quitting the access with AP;
   - Step 7, MT completing access with AP, and starting communication.
Contributory infringement

- All claimed steps are implemented by end user (MT) and other parties (AP and AS)
- Sony provides (MT) to end user
- Non-commercial purpose from the users
- Devices sold has no substantial non-infringing use
- "Normally on premise of direct infringement…but not necessarily, (contributing infringer liable) as long as all steps will be carried out if the end user follows the specification"
Exhaustion of Rights

- Neither Qualcomm or Sony has a license with the patentee for using the patented method.
- Statutory exhaustion does not cover method patent.
- Exhaustion rule of Beijing High Court covers method patent.

SEP Related Issues

- FRAND statement waives rights to sue? No
- Fault by licensee---injunction available
- For SEP, no claim chart is required for showing good faith, and for SEP patentee, requiring NDA before providing claim chart is reasonable.
Iwncomm v. Sony China (2017)

- **Damages**
  - **Reasonable royalty**
    - 4 license agreements (patent packages including other patents) with other licensees, 1 RMB per handset
    - Permitted number of handsets by government branch
  - **Royalty * 3 times, total RMB 8.5 million**
    - National science & technology award
    - Standardized technology
    - Sony’s fault by delaying negotiation
Sony appealed to Beijing High Court

- Decision was made on March 28, 2018
- The High Court agreed with all the rulings of Beijing IP Court but disagreed with the contributory infringement ruling.

“without a direct implementer, determining contributory infringement made by the provider of only one of the parts does not meet the requirements for the key element of contributory infringement and will jeopardize the public interest by excessively protect the right holder.”
Thank you!

Contact information:
Tel: 212-809-8100; Fax: 212-809-8118
Email: yyu@cptausa.com; newyork@cpahkltd.com
Canadian Patent Updates: Promise Utility Doctrine, Certificates of Supplementary Protection and Proposed PMPRB Changes

Arvie Anderson
ABA 33rd Annual Spring Meeting
April 19, 2018, Washington DC
When faced with allegations of a lack of patent utility, Canadian Courts did the following:

- Construed the “promise” of the patent
- Determined whether promise is demonstrated or soundly predicted
- Identified the factual basis for any prediction;
- Determined if a sound line of reasoning for any prediction
- Decided whether there was a factual basis and sound line of reasoning disclosed in the patent specification
Canadian Utility Requirements Prior to *AstraZeneca v Apotex* 2017 SCC 36 (cont’d)

- If demonstrated utility, evidence of utility need not be in the patent
- Focus on the “promise” of the patent with high thresholds:
  - Successful human use
  - Treatment of a chronic disease
- Courts scoured language in patent specification for promise interpretation
Test interpreted as: Did the inventors have a *prima facie* reasonable inference that the promise of the patent was met at the filing date

Patents found not to meet this test even though they disclosed tests in animals or even in humans
Canadian Utility Requirements Prior to *AstraZeneca v Apotex* 2017 SCC 36 (cont’d)

- Even if a factual basis and a sound line of reasoning – the patent could fail for a lack of sound prediction if these elements are not disclosed in the patent.
- A departure from previous approach which simply asked whether the patent teaches how to make and use the invention.
- Without disclosure of the factual basis and sound line of reasoning, the inventor is seen to be giving nothing to the public in exchange for the monopoly justifying patent invalidity on this basis.
Esomeprazole, sold under the name Nexium® by AstraZeneca, is a proton pump inhibitor (PPI) used to treat gastric diseases.

Canadian Patent No. 2,139,653 (CA 653) claims optically pure salts of esomeprazole.

In Patent Infringement action, Federal Court found the subject-matter of CA 653 to be novel and inventive, but held that the patent was invalid for lack of utility:

- Relying on the “promise of the patent”, Federal Court held that if the specification of a Canadian patent sets out an explicit promise of utility, then utility will be measured against that promise.
- In this case, CA 653 construed as containing two promises but found only one of the promises to have been met and, as a result, the patent was invalid for lack of utility.
AstraZeneca v Apotex 2017 SCC 36

• The Federal Court of Appeal upheld the Federal Court’s decision, concluding there was no demonstration of any legal error in the Federal Court’s construction of the promise

• AstraZeneca appealed to the Supreme Court on the issue of promise
  • Extra-statutory requirement of utility without any basis in law.
  • Multiple Interventions before the Supreme Court (for and against)
    • Promise doctrine had put Canada’s patent law out of step with international standards;
    • Changes to patent law to harmonize Canadian law with that of other major jurisdictions should be left to Parliament
    • Promise doctrine was rooted in well-established jurisprudence.
**AstraZeneca v Apotex 2017 SCC 36**

- The Supreme Court of Canada issued highly anticipated reasons in June 2017.
- Supreme Court rejected the “promise doctrine” as a method to determine whether the utility requirement in *Patent Act* was met.
- Supreme Court Held:
  - The subject-matter must be “capable of a practical purpose.”
  - Only one potential use of an invention needs to be realized even if additional uses are disclosed in the patent specification.
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AstraZeneca v Apotex 2017 SCC 36

• SC held that promise doctrine is an interpretation of the utility requirement that is incongruent with both the words and the scheme of the Act.
  • Counter to scheme of the Act by conflating the requirement that an invention be “useful” (under section 2) and the requirement to disclose an invention’s “operation or use” (under section 27(3)).
  • If multiple promised uses, to require that all those uses be met for the patent’s validity to be upheld is punitive and has no basis in the Act.

• SC held that proper approach to determine whether patent possesses utility is to
  • identify the subject-matter of the invention as identified by claims construction;
  • ask whether that claimed subject-matter is capable of a practical purpose.
  • Act does not prescribe the degree/quantum of usefulness: scintilla of utility will do.
  • Courts must ask whether that subject-matter is “capable of a practical purpose.”
  • Not every potential use of an invention needs to be realized, even if it is disclosed in the patent specification; only one will suffice.
Holding: The Supreme Court found the use of optically pure salts of esomeprazole as a PPI to be appropriately related to the subject-matter of CA 653

• Allowed the appeal declaring that CA 653 is not invalid for want of utility.
**AstraZeneca v Apotex 2017 SCC 36**

- Supreme Court indicates that overpromising in a Canadian patent is a mischief that may invalidate a patent because:
  
  “[a] disclosure which is not correct and full, or states an unsubstantiated use or operation of the invention, may be found to fail to fulfill the requirements of s. 27(3).”

- In addition, overpromising may result in a patent being void where such statements amount to an omission or addition that is “willfully made for the purpose of misleading,” under section 53 of the Act.

- Overall, the Supreme Court reaffirmed the primacy of claims in a Canadian patent. Following construction of the claims, it is against the subject-matter of claims that an allegation of lack of utility must be assessed.
Rejections of Attempts to Resurrect the Promise Doctrine


Lantech.com, LLC v Wulftec International Inc 2018 FC 41, Annis J

• Promise Allegation Fails To Survive A Motion to Strike
• Defendant Wulftec sought to amend SOC to add an allegation that the asserted patents are devoid of utility
• Plaintiff Lantech argued, inter alia, that the allegations were based on an alleged promise of utility in the patent description
• Annis J agreed with this submission and concluded that the proposed utility amendments did not meet the requirement of disclosing a reasonable cause of action.
AU Promise Doctrine Case


• Appeal against the lack of utility finding was successful, but only because the “promise” of the patent was interpreted more favourable to the patentee, not because the “promise” approach was found to be inappropriate.

• Accordingly, if a patentee promises that an invention will achieve two benefits, but the invention as claimed only achieves one of them, the claim will fail for lack of utility.

• Language used in the judgement that the presence of a single claim which does not meet the “promise” might be sufficient for the whole patent to be revoked. (See paragraph 239 of the decision)
Extensions of Patent Term in Canada

• Patent term restoration, up to two years, for patents relating to human and veterinary drugs containing a new medicinal ingredient, or a new combination of medicinal ingredients, protected by an eligible patent. (September 2017)

• Grant in the form of a certificate of supplementary protection (CSP), is intended to partly compensate for time spent in research and obtaining marketing authorization for new drugs.

• The new CSP regime has been implemented in order to meet Canada’s obligations under the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union.
Term of a CSP

• A CSP will take effect on the expiry of the original 20-year term of the corresponding patent. The term of a CSP is the difference between:
  • the date of the filing of the application for the patent and
  • the date of issuance of the authorization for sale (Notice of Compliance or “NOC”), reduced by five years, and capped at two years.

• CSP term = [(NOC date – Patent filing date) – 5 years] but not to exceed a 2-year maximum.
Eligibility for a CSP

• Objective of the CSP Regulations is to provide additional protection for drugs containing *new* medicinal ingredients and *new* combinations of medicinal ingredients “as such”. (not all drugs)

• CSP is only available where no other CSP has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients.

• Medicinal ingredients contained in drugs will be treated as being the *same* medicinal ingredient if they differ from each other only with respect to:
  • a variation in any appendage within the molecular structure of a medicinal ingredient that causes it to be an ester, salt, complex, chelate, clathrate or any non-covalent derivative;
  • a variation that is an enantiomer, or a mixture of enantiomers, of a medicinal ingredient;
  • a variation that is a solvate or polymorph of a medicinal ingredient;
  • an in vivo or in vitro post-translational modification of a medicinal ingredient; and
  • any combination of the above variations.

• These requirements ensure that only one CSP will be issued with respect to a given medicinal ingredient or combination of medicinal ingredients.

• Note, however, a patent that covers more than one medicinal ingredient or combination of medicinal ingredients would be eligible to support a CSP in respect of each of those medicinal ingredients or combinations.

• In addition, the medicinal ingredient or combination must not have been in a drug previously authorized for sale in Canada.
More on CSP Eligibility

• Not all patents will be eligible for a CSP. To be eligible, a patent specified in a CSP application must be in force at the time of the application for a CSP and at the time of grant of the CSP; and
  • include at least one claim that pertains to the same medicinal ingredient (or combination) contained in the drug for which regulatory approval is being sought;
  • the same medicinal ingredient (or combination) as produced by a defined process; or
  • any use of the same medicinal ingredient (or combination).

• Thus, by definition, patents directed to solely to processes and formulations are excluded.
Other CSP Requirements

• Not all marketing approval submissions will support an application for a CSP.

• To be eligible for a CSP, there is a requirement to coordinate the Canadian application for marketing approval (i.e. the NOC application) with any application for marketing approval for the *same* medicinal ingredient or combination that has already been filed in one of the following prescribed countries:
  • the European Union or any member country, the US, Australia, Switzerland, or Japan.

• If an application for marketing approval has already been filed in one of these countries, then the Canadian application for marketing approval must be made within a prescribed period of:
  • 24 months, if the application for a CSP was filed no later than the first anniversary of the day on which the CSP provisions come into force, and
  • 12 months, in any other case.

• This requirement incentivizes early introduction of new drugs in Canada, while still providing a reasonable transition period for innovators during the first year of the CSP regime.
CSP Deadlines and Fees

• An application for a CSP must be filed within 120 days of: (a) the day on which an NOC is granted (for an earlier granted patent), or (b) the day on which the patent issues (for an earlier granted NOC).

• There is a fee of $9,011 payable on filing an application for a CSP. Beginning on April 1, 2018, the fee will increase annually by 2% of the fee payable in the previous year.
Patented Medicines Price Review Board (PMPRB)

• An independent, quasi-judicial tribunal created in 1987 under the Patent Act

• Has a dual role
  - To ensure that prices charged by patentees for patented medicines, new and existing, under prescription or over the counter, for human and veterinary use, sold in Canada, to wholesalers, hospitals or pharmacies, are not “excessive” (not defined)
  - To report on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees
PMPRB Jurisdiction

- Most new patented drug prices are limited so the cost of therapy is in the range of the cost of therapy for existing drugs sold in Canada used to treat the same disease.

- Prices of moderate and substantial improvement drugs and breakthrough drugs are also restricted by a variety of tests.

- Existing patented drug prices cannot increase by more than the Consumer Price Index (CPI).

- The prices of patented medicines in Canada remain at the median of 7 comparator countries, i.e., France, Germany, Italy, Sweden, Switzerland, the UK and the US.
PMPRB Price Review

• PMPRB reviews pricing information on an on-going basis to ensure that the prices comply with the *Patent Act* and does so for the duration of the patent

• When Board Staff finds that the price of a patented drug appears to exceed the Guidelines, and where the criteria for commencing an investigation is met, an investigation will be conducted

• An investigation may result in one of the following situations:
  - The closure of the file, where it is concluded that the price was within the Guidelines;
  - A Voluntary Compliance Undertaking (VCU) by the manufacturer to reduce the price and take other measures to comply with the Guidelines; or
  - A public hearing to determine if the price is excessive and, if so, the issuance of a remedial order by the Board to reduce the price and to offset up to double excess revenues it may have received
PMPRB Jurisdiction

• **Patent Act**
  - Section 83(1) “Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board’s opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive…”
  - Section 79(2) “…an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine.”

• **ICN Pharmaceuticals Inc v Canada (Staff of the Patented Medicine Prices Review Board), [1997] 1 FC 32 (FCA)**
  - Must be a rational connection or nexus between the invention and medicine
  - Burden of proof is “merest slender thread of connection”
  - To be decided only on the face of the patent
  - Board is not to engage in patent or claim construction or infringement analysis
Galderma v Attorney General of Canada, 2017 FC 1023

• In November 9, 2017 decision, Justice Phelan of the Federal Court found that PMPRB was unreasonable in its assessment that a patent ‘pertained’ to Galderma Canada’s DIFFERIN (0.1% adapalene), as the Board failed to consider the entire patent

• The key issue before the Board was whether the “pertains” requirement had been met, i.e., whether the invention claimed and described in the “pertains” to DIFFERIN

• Recently filed AG of Canada brief argues “medicine” can refer to the active medicinal ingredient and not just the brand name per ICN

  • AG argued that the “merest slender thread” is a very low threshold for jurisdiction

• Galderma’s factum is due [Apr. 21, 2018]
PMPRB Changes are Coming!

- PMPRB’s 2015-2018 Strategic Plan
  - Jun. 2016 Guidelines Modernization (PMPRB)
  - Dec. 2017 Proposed amendments (Health Canada)
  - Jan. 2019 Implementation

- Key changes proposed
  - To introduce additional factors in assessing whether the price of a patented medicine is excessive (e.g., pharmacoeconomic value of medicine, size of market in Canada and other countries, GDP and GDP per capita in Canada)
  - To revise the list of comparator countries (e.g., excluding US and Switzerland and including Australia, Belgium, Japan and S. Korea)
  - To relieve generic drugs, over the counter products and veterinary products from reporting price and sales information unless by request
  - To require patentees to provide every cost-utility (pharmacoeconomic) analysis within 30 days of the earlier of the first day of sale or publication of the analysis
  - To require patentee to calculate the average price of a medicine by taking into account “any adjustments that are made by the patentee or any party that directly or indirectly purchases or reimburses for the purchase of the medicine”
Discussion
Coming Together: Worlds Apart

European patent developments

Nick Bassil - Kilburn & Strode LLP

19 April 2018
Overview

– Europe
  – Success of EPO system and push for EU patent
  – BREXIT: the UK leaves the EU
  – Unified Patent Court (UPC) and Unitary Patent
    – Brexit and the German Court challenge
  – Effect on harmonisation of patent systems in Europe
1

BREXIT – UK leaves the European Union
The UK leaving the European Union: a dynamic process

- Brexit day: 29 March 2019
- Transition period expires: 31 December 2020 (?)
The UK leaving the European Union: a dynamic process

Before: UK in European Union but with a lot of opt-outs

After: UK not in European Union but a lot of opt-ins (?)
BREXIT – update and challenges

- Status
  - Brexit by operation of law – effect of declaration under Article 50 TFEU
- IP issues after Brexit
  - Patents: none
  - EU Trade marks and EU Registered Designs, PDGO/PDGI: mostly resolved or proposed draft agreement in Withdrawal Treaty
  - Supplementary Protection Certificates (SPCs)
BREXIT – update and challenges

– European Patent Office (EPO) is governed by European Patent Convention (EPC)
– UK member of European Patent Convention (EPC) since 1973
– EPO not a European Union (EU) institution
– “Brexit” has no effect on UK membership of EPC or participation in the EPO
BREXIT – update and challenges

– Current moves to harmonise patent law in Europe at national IPO/EPO level will not be affected by “Brexit”
  – UK remains part of the EPO
  – Existing judicial approaches to harmonisation likely to continue amongst national states and EPO

– But…. For Unified Patent Court/Unitary Patent impact of Brexit could be serious
Unitary Patent and Unified Patent Court in Europe
Unitary Patent and Unified Patent Court (UPC) Agreement update

- Summary – pros/cons
- Forum shopping under the UPC
- Status
- Problems
- Checklists
Unitary Patent: advantages/disadvantages

– Option at the grant stage of a European patent application
  – Select unitary patent protection to get a Unitary patent (one month deadline), or
  – Follow national validation process to get standard European patents in national states (3 month deadline), or
– Combination of Unitary protection and national validations (for non-participating states)
Unitary Patent: advantages/disadvantages

– Avoids (reduces) national validation formalities with Unitary patent compared to standard EP patent
– But will still need national validations of European patents for states not part of Unitary patent system
  – e.g. EU states not taking part: ES, PL, HR
  – e.g. Non-EU states: CH, NO, TR, etc. (…and presumably GB in due course)
– And Unitary protection only available for UPC states (so watch out in early years!)
Unitary Patent: advantages/disadvantages

- Expensive renewal fees in later years of Unitary patent life but is more cost effective in early years than national validations (“top 4” calculation)
- Opt-in/opt-out procedure for standard European patents from UPC jurisdiction
  - Opt-out/-in procedure available for 7 years (may be extended for further 7 years) - after UPC starts
  - n.b. “sun-rise” period for opt-outs starts 3 months before court starts work
Unified Patent Court (UPC): advantages

– Common patent court to hear single dispute on same patent in Europe
  – Unitary patent or standard European patent
    – Unless standard EP opted-out
  – SPCs granted on basis of a European patent
– Preliminary injunctions
– Discovery – civil search orders
– Protective letter system
Unified Patent Court (UPC): disadvantages

– European patents vulnerable to central revocation for entire lifetime (not just opposition period)
– Provides potentially effective forum for patent assertion entities in Europe
– Unknown panels of multinational judges
  – Less predictability than national judges?
Forum shopping under the UPC

– UPC will allow forum shopping (as at present in the national court system) between local/regional divisions and the Central Division

– But…

– In theory the mixed nationalities on the judicial panels should result in greater harmonisation (?)
Forum shopping under the UPC

- Revocation
  - Central Division
    - London, Paris, Munich

- Infringement
  - Local/Regional Division but can transfer to Central Division
  - Can include a counterclaim for revocation
  - Can bifurcate
UPC Local/Regional Divisions

- **Local Divisions**
  - Germany (4), Italy, UK, Ireland, Austria, Denmark, Belgium, Netherlands, Finland

- **Regional Divisions**
  - Nordic-Baltic (Sweden, Estonia, Latvia, Lithuania)
UPC Central Division

- **Paris**
  - Performing operations, Transport, Textiles & Paper, Physics, Electricity, Telecom

- **London**
  - Human Necessities, Chemistry, Metallurgy, Pharma & Biotech

- **Munich**
  - Mechanical Engineering, Lighting, Heating, Weapons, Blasting
Unitary Patent and Unified Patent Court (UPC) Agreement update

– Status of ratification process
  – UPC Agreement to come into force after 13 ratifications including DE, FR & GB
  – 15 states as of April 2018, including FR
  – Only waiting for DE and GB….
    – GB nearly there as is DE
    – But also need two Protocols to be ratified also
Unitary Patent and Unified Patent Court (UPC) Agreement update

– Protocol on Provisional Application (PPA) needs to be ratified by 13 states including FR, DE, GB
  – 6 to 8 month provisional application phase before court opens
  – Includes 3 month “sun-rise” period for opt-outs
– Protocol on Privileges and Immunities (PPI) needs to be ratified by 13 states including LU, FR, DE, GB
  – Required for legal personality etc.
Unitary Patent and Unified Patent Court (UPC) Agreement update

– Slow pace of UPCA, PPA, PPI ratifications means that there will be time to prepare before UPC starts work

– But…..

– Possibility that Brexit and/or DE Constitutional Court challenge could derail whole process of implementation of UPC system
Unitary Patent and Unified Patent Court (UPC) Agreement update

– The British problem
  – BREXIT: 29 March 2019 (up to 31 Dec 2020)
  – If the UPC is an international agreement can UK still participate?
  – If the UK still takes part, can the UPC Central Division have a seat in London?
  – CJEU Opinion 1/09 & CJEU jurisdiction
  – What happens to Unitary patents designating the UK?
Unitary Patent and Unified Patent Court (UPC) Agreement update

– The German problem
  – Constitutional Court reference
  – How long is this going to take?
  – What happens next?
    – Could decision happen after Brexit date?
  – Referral to CJEU?
Unitary Patent and Unified Patent Court (UPC) Agreement update

– Checklists
  – Identify important granted standard European patents for potential opt-out from UPC
  – Identify important pending standard European patent applications for potential opt-out from UPC
  – Decide strategy for dealing with grant of standard European patent or a Unitary patent
  – Review licence agreements for choice of forum language, IP rights definitions etc.
Unitary Patent and Unified Patent Court (UPC) Agreement update

- UPC good for:
  - Litigious companies with large portfolios of patents
  - Patent licensing/assertion entities

- UPC not good for:
  - Risk averse companies nervous of new forum
Strategies to avoid the UPC

– Opt-out existing standard European patents from UPC jurisdiction

– Only validate European patents as standard European patents nationally and select opt-out (for as long as opt-out possible);
  – consider EP divisional filings to get both UP/EP

– File national patents

– But remember national route from PCT applications “closed” for some states, e.g. FR but not GB, DE
Harmonisation in Europe

– Judicial cooperation between national judges in Europe will continue
– Cooperation between National Patent Offices and EPO will continue
– Introduction of UPC/Unitary Patent will add to these moves
– Brexit is not making life easier, but it’s not a roadblock to progress either
Thank you

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