Canadian Patent Updates:
Promise Utility Doctrine, Certificates of Supplementary Protection and Proposed PMPRB Changes

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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
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
AstraZeneca v Apotex 2017 SCC 36

- 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.
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.
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.
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

• *Pfizer Canada Inc. v Apotex Inc.* 2017 FC 774 Brown J 2,436,668 / desvenlafaxine (ODV) / PRISTIQ / NOC

• 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.
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

• Patented Medicine Prices Review Board (PMPRB) controls price over which patented medicines are sold in Canada

• Patent grant triggers jurisdiction
  • Once granted, PMPRB is assuming jurisdiction over price at which medicine sold

• Broad jurisdiction
  • “merest slender thread” of a connection between patented invention and medicine sold in any market in Canada
  • Patent may pertain to a medicine where invention is merely capable of being used for the preparation or production of the medicine
Proposed PMPRB Changes

• Price Regulatory factors
  • Pharma - economic value of the drug in Canada,
  • market size for the drug in Canada and other countries, and
  • Gross domestic product (“GDP”) in Canada and GDP per capita in Canada.

• Updated schedule of international price comparator countries
  • The proposed schedule lists: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden and the United Kingdom (“PMPRB12”), while removing Switzerland and the United States from consideration.

• Reduced Reporting Requirements for OTC and Generic Drugs
• Updated Reporting Requirements for Patented Medicines
• Obligation to Report all discounts and rebates