Table Comparing the Patent Law Regimes – TPP vs. Canada, Mexico, and NAFTA

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Summary of the Table

- **Requirements of Patentability**
  - **Novelty**
    - TPP, Canada, Mexico, and NAFTA all require the invention (product or process) to be "new" or "novel".
  - **New Uses**
    - TPP requires patents for any new forms, uses, or methods of using a known product.
    - Canada does not allow patenting of medical *methods* but allows patenting of new *uses* (use claims).
    - Mexico does not allow patenting of new uses or new forms of known inventions or materials.
  - **Inventive Step (Non-Obviousness)**
    - TPP, Canada, Mexico, and NAFTA all require some form of inventive step (non-obviousness) for patents.
  - **Industrial Application (Usefulness)**
    - TPP, Canada, Mexico, and NAFTA all require some form of industrial application (usefulness) for patents.

- **Patentable Subject Matter**
  - TPP mandates making patents available for "plants and animals" and "diagnostic, therapeutic, and surgical methods for the treatment of humans or animals".
  - Canada does not allow patenting of certain plants and also does not allow patenting of medical (therapeutic and surgical) methods. However, Canada allows patenting of diagnostic methods.
  - Mexico does not allow patenting of "animal breeds" and "plant varieties". Additionally, Mexico does not allow the patenting of "surgical and therapeutic treatment or diagnostic methods applicable to the human body and to animals."
  - NAFTA allows parties to exclude from patentability, "plants and animals other than microorganisms" as well as "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."

- **Patent Term Extensions**
  - TPP requires members to grant extension of patent terms beyond the TRIPS 20 year minimum.
  - Canada limits patent terms to 20 years from the filing date for patents filed on or after Oct. 1, 1989.
  - Mexico limits patent terms to 20 years from the filing date.
  - NAFTA allows patent term extensions.

- **Data Exclusivity**
  - TPP, Canada, Mexico, and NAFTA all abide by the 'minimum data exclusivity protection of 5 years', as required under NAFTA. Canada does not offer data exclusivity for drugs that contain medicinal ingredients that have been previously approved, as required by the TPP.
- **Patent Linkage**
  - TPP, Canada, and Mexico all have some form of patent linkage system. Patent linkage is not dealt with in NAFTA.

LEGAL ISSUES	TPP[1] or TPP-2 (Selected Provisions)[2]	CANADA	MEXICO	NAFTA
Requirements of Patentability -Novelty -New Uses	TPP Art. 8.1 – "Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application.[15] In addition, the Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product."	-Patent Act – Sec. 2 – "'invention' means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter." --- -Patent Act – Sec. 28.2 – "(1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed." --- -Medical Methods NOT Allowed – *Tennessee Eastman Co. et al. v. Commissioner of Patents, [1974] S.C.R. 111* – "Court rejected a claim relating to a surgical procedure, holding that the methods of medical treatment do not produce a result in relation to trade, commerce or industry nor a result that is essentially economic."[3] --- -New Uses ("Use Claims") ARE Allowed – *Shell Oil Co. v. Commissioner of Patents* – "In this case, the Court held that a new use of a known compound was an 'invention' because it 'involved the application of new knowledge to effect a desired result which had undisputed commercial value.'"[4]	-"Patents can protect a product, process, apparatus or means specially devised for its application, and combinations thereof; the requirements are novelty, inventive step, and industrial applicability."[5] --- "Article 12 of the Industrial Property Law (IPL) defines 'novel' as anything not found in the prior art; 'prior art' as all the technical knowledge that has been made public by oral or written means, by use or by any other dissemination or information means, either in Mexico or abroad."[6] --- -New Uses NOT Allowed with Exceptions: - "The following shall not be considered inventions: • the juxtaposition of known inventions or mixtures of known products, or alteration of the use, form, dimensions or materials thereof, except where in reality they are so combined or merged so that they cannot function separately or where their	Art. 1709(1) 1. Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful", respectively.

[1] http://infojustice.org/download/tpp/tpp-texts/tpp%20IP%20chapter%20feb%20leak.pdf
[2] http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf
[3] http://www.blaney.com/sites/default/files/Patent-Applications_JC_dec2010.pdf
[4] http://www.blaney.com/sites/default/files/Patent-Applications_JC_dec2010.pdf
[5] http://www.latinlawyer.com/reference/topics/52/jurisdictions/16/mexico/
[6] http://www.latinlawyer.com/reference/topics/52/jurisdictions/16/mexico/

			particular features or functions have been so modified as to produce an industrial result or their use is not obvious to a person skilled in the art."[7]	
Requirements of Patentability -"Inventive step (non-obvious), -"Is capable of industrial application (useful)"	TPP FN15 – ". . . a Party may treat the terms "inventive step" and "capable of industrial application" as being synonymous with the terms "non-obvious" and "useful," respectively. In determinations regarding inventive step (or non-obviousness), each Party shall consider whether the claimed invention would have been obvious to a skilled artisan (or a person having ordinary skill in the art) at the priority date of the claimed invention."	Patent Act – Sec. 2 – "'invention' means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter." ---------- Patent Act – Sec. 28.3 – "The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains . . ."	-The requirements for patent protection are novelty, inventive step, and industrial applicability. "Art. 12 of the Industrial Property Law (IPL) defines 'inventive step' as the creative process where the results are not obvious, from the prior art, to a person skilled in the art. An invention is obvious if a person skilled in the art would have modified the relevant prior art to obtain the invention as a whole based on factors such as common general knowledge, disclosures in the prior art, the technical problem to be solved and/or technical effects." [8]	Art. 1709(1) 1. Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful", respectively.
Patentable Subject Matter	TPP Art. 8.2 – mandates making patents available for "plants and animals" and "diagnostic, therapeutic, and surgical methods for the treatment of humans or animals". TPP Art. 8.3 – "Each Party may only exclude from patentability inventions, the prevention within its territory of the commercial exploitation of which is necessary to protect ordre public or morality,	-Certain Plants are NOT Patentable – *Pioneer Hi‑Bred Ltd. v. Canada (Commissioner of Patents), [1989] 1 S.C.R. 1623* – "It is true that most countries give the producers of new plant varieties special protection; even in Canada, several legislative proposals for this purpose have appeared over the years. Though this kind of legislation might act as a catalyst in the development of scientific research in Canada, I consider that this Court does not have the right to stretch the scope	-"Novel inventions resulting from an inventive step and subject to industrial applicability shall be patentable, with the exception of: • essentially biological processes for obtaining, reproducing and propagating plants and animals; • biological and genetic material as found in nature; • animal breeds;	Arts. 1709(2), (3) 2. A Party may exclude from patentability inventions if preventing in its territory the commercial exploitation of the inventions is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that the exclusion is

[7] http://www.latinlawyer.com/reference/topics/52/jurisdictions/16/mexico/
[8] http://www.latinlawyer.com/reference/topics/52/jurisdictions/16/mexico/

	including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law."	of patent protection beyond the limits of existing legislation. Accordingly, since the Patent Act contains no provisions relating directly to biotechnological inventions and new forms of life in particular, this new soybean variety will only be patentable if it meets the traditional conditions and requirements for a patent."[9] --- Medical Methods (Therapeutic and Surgical) NOT Allowed – *Tennessee Eastman Co. et al. v. Commissioner of Patents, [1974] S.C.R. 111* – "Court rejected a claim relating to a surgical procedure, holding that the methods of medical treatment do not produce a result in relation to trade, commerce or industry nor a result that is essentially economic"[10] (Although substances intended for medicine is now patentable, the prohibition against patentability of methods of medical treatment still holds.) --- Diagnostic Methods ARE Patentable – *Re Application of Kevin McIntyre* – "claims to a method of evaluating the mechanical condition of a heart were patentable."[11] *Re Application of Goldenberg* – "claims that involved methods of detection and localization of a tumor without medically treating the tumor are patentable." [12]	• the human body and the living matter constituting it; and • plant varieties. The following shall not be considered inventions: • findings that consist of making public or disclosing something that already existed in nature, even though it was previously unknown to man; . . . . • surgical and therapeutic treatment or diagnostic methods applicable to the human body and to animals; and • the juxtaposition of known inventions or mixtures of known products, or alteration of the use, form, dimensions or materials thereof, except where in reality they are so combined or merged so that they cannot function separately or where their particular features or functions have been so modified as to produce an industrial result or their use is not obvious to a person skilled in the art."[13]	not based solely on the ground that the Party prohibits commercial exploitation in its territory of the subject matter of the patent. 3. A Party may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than microorganisms; and (c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production. Notwithstanding subparagraph (b), each Party shall provide for the protection of plant varieties through patents, an effective scheme of sui generis protection, or both.

[9] Pioneer Hi-Bred v Canada (Commissioner of Patents) [1989] 1 S.C.R. 1623 at 1642
[10] http://www.blaney.com/sites/default/files/Patent-Applications_JC_dec2010.pdf
[11] http://www.blaney.com/sites/default/files/Patent-Applications_JC_dec2010.pdf
[12] http://www.blaney.com/sites/default/files/Patent-Applications_JC_dec2010.pdf
[13] http://www.latinlawyer.com/reference/topics/52/jurisdictions/16/mexico/

Patent Term Extensions	TPP-2 Art. 8.6 –would require TPP members to grant extensions of patent terms beyond the TRIPS twenty year minimum patent term to compensate both for delays in patenting and in granting marketing approval.	Patent Term Extensions are NOT Allowed -Patent Act – Sec. 44 – ". . . where an application for a patent is filed under this Act on or after October 1, 1989, the term limited for the duration of the patent is 20 years from the filing date."	-"The patent term lasts 20 years, starting from the filing date."[14]	-Patent Term Extensions ARE Allowed -Art. 1709(12) – "Each Party shall provide a term of protection for patents of at least 20 years from the date of filing or 17 years from the date of grant. A Party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes."
Data Exclusivity	TPP-2 – Art. 9.2 • 3-year data exclusivity period for Pharmaceutical Product that includes a Chemical Entity that has been Previously Approved for marketing in Another Pharmaceutical Product; • 5-year data exclusivity for new Pharmaceutical Product TPP-2 – Art. 9.7 – "Where a Party provides for a period of data protection for a pharmaceutical product of more than [5+Y] years pursuant to subparagraph 2(a) or 2(b) of this Article, that Party is not required to implement for that pharmaceutical product subparagraphs 2(c), 2(d) (3-year data protection in connection with submission of new clinical information), 5(b)(i) (automatic delay of marketing approval) or 5(d) of this Article (reward for the	Canada's data protection regime under Section C.08.004.1 (the Data Protection Regulation) of the Food and Drug Regulations, C.R.C., c. 870 (the FDA Regulations) provides "innovative drugs" with: • 6-year data exclusivity period; • 8-year market exclusivity period; and • additional 6-month period of market exclusivity in some cases for pediatric applications.[15] **BUT NOTE:** "Under the definition of an innovative drug, drugs that contain medicinal ingredients that have been previously approved in Canada, including drugs that have previously received an NOC and/or a Drug Identification Number (DIN), will not be afforded protection under these provisions."[16]	- "No data exclusivity in patent legislation, but protects data for five years as established in the NAFTA Art. 1711."[17]	-NAFTA Data Exclusivity Terms are "reasonable period" normally meaning not less than 5 years. Arts. 1711(5)-(7) 5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is

[14] http://www.latinlawyer.com/reference/topics/52/jurisdictions/16/mexico/
[15] SOR/95-411, s. 6; SOR/2006-241, s. 1, effective October 5, 2006 (Can. Gaz. Pt. II, Vol. 140, No. 21, p. 1493).
[16] http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/data_donnees_protection-eng.php
[17] http://www.unescap.org/tid/projects/trips2012-who.pdf

	successful challenge of the validity or applicability of a patent).”			protected against unfair commercial use. 6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable ***period of time*** after their submission. For this purpose***, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them***. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies. 7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

Patent Linkage	TPP-2 – Art. 9.5 Links marketing approval to patent status.	"Canada has a system similar that of the U.S. FDA, where health regulatory authorities will not provide marketing approval for pharmaceutical products protected by patents listed in the equivalent of the FDA Orange Book."[18]	"Applicants seeking marketing approval for generic pharmaceutical products in Mexico must certify that they that patent rights are not infringed. Health regulatory authorities then check with the patent office, which must respond within ten days to confirm whether a patent is involved. While health authorities will accept an application of marketing approval during the patent period, grant of marketing approval will be delayed until the patent expires."[19]	Linkage is not dealt with in NAFTA.

[18] http://www.finstonconsulting.com/version03/files/Overview.pdf
[19] http://www.finstonconsulting.com/version03/files/Overview.pdf