A Comparative Overview of Canadian, US and European Pharmaceutical Patent Systems

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IPIC is pleased to provide the following comparison of the patent regimes of Canada, the United States and Europe, with an emphasis on issues of relevance to biotechnology and pharmaceutical subject matter. As this document provides an overview of key similarities and differences in the patent regimes of these regions, it may assist in providing context behind certain demands in trade agreement negotiations, for example, as may occur in discussions between Canada and the European Union with regard to the Comprehensive Economic and Trade Agreement (CETA). However, as IPIC has not been privy to any official version of CETA text, the material presented regarding CETA is for general informational purposes only and should not be relied on for the analysis of any specific fact situations. Also, the references to specific CETA article numbers may no longer be accurate.

The material below relates to several different national legal systems, and consequently there are instances where IPIC is not qualified to comment definitively regarding the situation in particular jurisdictions.

This document was prepared by a subcommittee of the IPIC Biotechnology Patents Committee and was reviewed, edited and approved by IPIC's governing Council.

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I. General Issues[1]	Patent law is national (subject to certain regional treaties: see the discussion of Europe, below), but the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has harmonized the law at the general level. Generally, patents are available (with some specified exceptions) for inventive products or processes in all fields of technology so long as the invention is new, involves an inventive step and is useful (or, equivalently, is capable of industrial application). The TRIPS agreement requires that patents shall be enjoyable without discrimination as to the place of making the invention, the field of technology and whether products are imported or locally produced (TRIPS, Article 27). Patentees will normally wish to patent an important invention in more than one country. International treaties to which Canada is signatory facilitate this by allowing a patent applicant in one country to base its application on and "claim priority" from an earlier filing in another country, so long as the second application is filed within one year of the first. The country in which the patent application is originally filed is referred to as the country of first filing, and the country in which a subsequent application is filed which claims priority to the first, is referred to as the country of second filing. Generally, Canada is a country of second filing, in that most Canadian patent applications claim priority from a first filing in another country, particularly the US or Europe. The various national patents based on a single application are referred to as a patent family. Even though a single original application may be the basis for a patent in several different countries, the application must be pursued (prosecuted) separately in each country and amendments to an application, especially amendments to the claims, are common. Consequently, each national patent in a single patent family may have a different scope of protection for an invention and individual patents issued within the same patent family are often slightly different at a detailed level.		
Legislation	Canadian law is found primarily in the *Patent Act*, as interpreted by the courts. The Act was significantly amended by RSC 1985 c 33 (3rd Supp), and the Act as amended applies to patents which were applied for after 1 Oct 1989. The amended Act is often referred to as the "new Act". One of the major changes implemented by the new Act was to move from a first-to-invent to a first-to-file system (see below). While some "Old Act" patents are still in effect, this comparison will focus on the new Act.	US law is found primarily in title 35 of the US Code, as interpreted by the courts. The *America Invents Act* significantly amends the 35 USC. The AIA was signed into law on September 16, 2011. One of the major changes implemented by the AIA was to move from a first-to-invent to a first-inventor-to-file system (see below). While not all of the provisions of the AIA have yet come into effect, this comparison will focus on US law as amended by the AIA, as that reflects current US thinking and will soon reflect US law.	European law is a hybrid system based on the European Patent Convention (EPC). The EPC sets out substantive law, similar to our *Patent Act*, and also sets up the framework for the administration of the EPC. Under the EPC system, patents are examined and granted centrally, by the European Patent Office (EPO), according to the law set out in the EPC. Patents granted by the EPO are commonly referred to as European patents, though it should be noted that membership of the EPC is not co-extensive with the European Union. All members of the European Union are also members of the EPC, but there are several countries that are members of the EPC but which are not members of the EU. Once granted, a European patent is only enforceable according to national law of an EPC country in which the patent has been validated. For example, if a patentee believes someone is infringing its patent in both the UK and Germany, it will have to sue in both countries. While national patent law of all EPC countries has been harmonized with the EPC,

			the courts in different countries may interpret that law differently. Courts may also come to different conclusions based on the different evidence that happens to be presented in litigation in different countries. It therefore may happen that the same European patent will be declared valid in one EPC country and invalid in another country. There have long been attempts to create a true European patent which would be unitary after being granted. Agreement on important points was reached in the past few months at the European Council level, and it is possible that a true unitary patent system will be implemented in Europe within the next few years.
Role of Patent Office	The Patent Office in each jurisdiction examines patent applications with the goal of ensuring that the application discloses and claims an invention for which the applicant is entitled to receive a patent under the laws of that jurisdiction. If the relevant Patent Office is so satisfied, the patent is granted. In Canada and the US, a decision by the Patent Office to refuse a patent may be appealed to the courts, ultimately to the Supreme Court of Canada or the United States. In Europe, the EPO has its own internal appeal system, and decisions of the EPO Boards of Appeal cannot be appealed to the national courts. The Patent Offices have guidelines reflecting their understanding of the law. Patent examiners consult these manuals in assessing applications. These are the Manual of Patent Office Practice (MOPOP) in Canada; Manual of Patent Examining Procedure (MPEP) in the US; and Guidelines for Examination in the European Patent Office. While these publications do not have the force of law, they set out examination policy and guide examiner decisions. They are therefore important in determining whether the Patent Office will be willing to grant a particular patent, and are therefore important to patent applicants.		
Novelty	To be patentable, an invention must be new. In all jurisdictions this is a strict requirement. The invention will be considered new unless the very same invention has been previously publically disclosed. Novelty (whether the invention is new) is assessed as of a particular date in time, which is called the “claim date” in Canada, and more generally, the “priority date.” This is normally the date on which the first application is filed. Disclosure of the invention after the priority date does not matter (subject to possible challenges based on the invalidity of the priority claim); disclosure before the priority date will invalidate the patent (the patent will be “anticipated.”). For example, an inventor can create a novelty bar to a patent on their own invention, by giving a paper at a conference in which the invention is discussed, or by publically installing an experimental version of the invention. Normally, therefore, an inventor or applicant should keep their invention confidential until they have filed a first patent application. To “anticipate” a claimed invention (i.e. to render it “not new” or not novel), the prior disclosure must be non-confidential. The inventor can raise money by disclosing its invention to investors, for example, so long as the disclosure is strictly confidential. Most countries enforce an “absolute novelty” requirement, and in these countries a non-confidential disclosure creates an automatic and immediate bar to patentability. The United States and Canada have a qualified absolute novelty system wherein an inventor can validly file an application up to one year after their first non-confidential disclosure of the invention. In the case of conflicting applications for the same invention, the first filed application will act as a novelty bar to the later application.		

Grace period See CETA Article 9.3 where Canada proposes a 12-month grace period. No change to Canadian law would be required if that proposal were accepted. Note that the precise nature of the grace period is not specified. Presumably a Canadian-style grace period was intended, but Art 9.3 would also be satisfied by a US style grace period.	If an inventor non-confidentially discloses their invention that disclosure will not be considered prior art, and so will not "anticipate" the invention, so long as the inventor files their application within one year of that first disclosure. Note that the Canadian grace period applies only to Canadian applications. If a Canadian inventor publically discloses their own invention prior to applying for a patent, the inventor will be able to take advantage of the Canadian grace period by filing a suitable Canadian application within one year, but they will not be able to obtain a European patent.	An inventor is granted a one year grace period from the first non-confidential disclosure of the invention to file a patent application in the United States. This is similar to Canada in that both systems provide that disclosure by the inventor will not count as prior art if the inventor subsequently files within the grace period. However, the new *America Invents Act* (AIA) provides that *any* disclosure of the subject matter of that invention during the grace period will not count as prior art, including disclosure by independent parties. In contrast, in Canada, disclosure by a third party during the grace period *will* count as prior art. Note that the US grace period applies only to US applications.	There is no general grace period for disclosures by the inventor, and a non-confidential disclosure normally raises an immediate and automatic bar to patentability. There are some very limited grace periods provided, for example, where there is a breach of confidentiality, but these will be relevant only in unusual circumstances.
First-to-file/first-to-invent	In a first-to-file patent system, if two individuals invent the same invention, the first to file their patent application will be entitled to the patent. In a first-to-invent system, the patent will be awarded to the individual who first invented the invention, after a special proceeding is held to make that determination. Almost all countries except the US now use a first-to-file rule, and the US will be adopting the first-to-file rule in March of 2013.		
Public disclosure	Public disclosure by others before the priority date is citable.	Public disclosure by others before priority date is citable.	Public disclosure by others before priority date is citable.
Co-pending applications may be citable	Co-pending applications may be citable.	Co-pending applications may be citable.	Co-pending applications may be citable.
Inventive step/ Obviousness	All patent systems require that an invention be inventive in order to be patentable. This is intended to ensure that the technical advance disclosed by the patent is something that deserves the reward of a patent monopoly, and not a routine advance that would have been arrived at in any event. In all three jurisdictions, an invention is considered to involve a sufficient inventive step if, having regard to the state of the art, the invention would not have been obvious to a person or ordinary skill in the art. While this concept is clear and well-established in all jurisdictions, it is a standard which is often difficult to apply to the facts of a particular case. While there are differences between the jurisdictions in the details of how the courts determine whether an invention would have been obvious to a skilled person, it is not clear whether the inventive step requirement is systematically more or less stringent in any particular jurisdiction. The uncertainty inherent in the application of the test to any set of facts makes it difficult to determine if there are systematic differences. Even when the same patent is held to be obvious in one jurisdiction but not in others, this may be simply because of the uncertainty in the test itself, and the way the evidence was weighed by a particular judge, rather than because the legal standard is systematically differently applied. Broadly speaking, the grace period applies in the US and Canada with respect to obviousness in the same way that it applies with respect to novelty. However, a pending patent application may not be citable for obviousness as of the same date on which it becomes citable for novelty.		

Statutory Subject Matter	An invention will also be assessed to determine if it is based on patent-eligible, also called statutory, subject matter. An invention that is not based on statutory subject matter will not be eligible for patent protection even if it satisfies all the other requirements for patentability (i.e. it is new, useful and inventive. In both Canada and the US, limitations on what constitutes patent eligible subject matter have arisen largely on the basis of judicial interpretation of the statutory definition of "invention" (which is similar in both jurisdictions). In Europe, the EPC provides a much more specific definition of patentable inventions (Art 52) and exclusions from patentability (Art 53) but this definition is also ambiguous in important respects. In all three jurisdictions there remains some uncertainty as what constitutes patent eligible subject matter. In part this is because the interpretation of the statutory provisions is unclear in some respects, and in part because it is often difficult to determine whether a particular invention falls within a particular enumerated category of patent eligible subject matter or whether it falls within a category of excluded subject matter. All three jurisdictions prohibit patents on mere ideas and discoveries themselves, but there is considerable uncertainty as to where to draw the line between a simple idea (not patentable) and the implementation of an idea (may be patentable). The problems of statutory interpretation are compounded by the fact that the subject matter of patent applications may be related to forms of technology that did not exist and could not have been contemplated at the time when the legislation was enacted.		
Business methods	The patentability of business methods was the subject of the 2011 decision of the Federal Court of Appeal in *Amazon.com*, which dealt with Amazon.com's application for a patent for one-click shopping.[2] The Court of Appeal held that business methods may be patentable, depending on how the claim is interpreted. The Patent Office subsequently granted Amazon.com's application for the one-click patent. The Patent Office is currently revising its examination policy in light of the Amazon.com decision.	The patentability of business methods was the subject of the 2010 decision of the US Supreme Court in *In re Bilski*[3], which dealt with a method for hedging risk in commodity trades. The US Supreme Court held that the invention in question was not patentable subject matter. However, the guidance provided by the US Supreme Court was not entirely clear, and considerable uncertainty remains as to whether any particular business related invention is patentable.[4] It is generally accepted that applications directed to methods of doing business are more commonly allowed in the US than elsewhere.	Under EPC Art 52, "schemes, rules and methods for. . .doing business" are not patentable "as such." The case law interpreting what it means for an invention to claim a method for doing business "as such" is not clear. However, it is generally accepted that applications directed to business methods are far less likely to be allowed in Europe than in the US.
Claim Construction	The patent claims define the scope of the patent monopoly, and so tell potential infringers what they can and cannot do, assuming the patent is valid. Claim construction is the process used by the courts to determine the scope and meaning of the language of the claims in a particular case. By analogy with land, claim construction turns lines on a map into lines on the ground. Claim construction often determines the outcome of litigation.		
Disclosure	The patentee must disclose the invention in a manner that is sufficiently clear and complete for it to be carried out by a person skilled in the art. This is known as an "enabling" disclosure.		
Remedies	The remedies available to a patentee that has prevailed at trial are the practical vindication of their rights. Consequently, the strength and availability of the various remedies is very important in determining the overall strength of the patent right.		
Damages See CETA Article 21. This article requires no change to Canadian law.	Damages are the standard remedy for patent infringement. The goal of damages is to compensate the patentee for the loss it has suffered as a result of the infringement. Damages are measured by the patentee's lost profits, and if the patentee has not lost profits directly (if, for example, the infringer was selling into a market in which the patentee did not compete), the patentee will be entitled to a reasonable royalty. While the general principles of damages are the same in all jurisdictions, there is considerable variation in the detailed rules used by the courts to calculate damages. This can result in significant differences between the jurisdictions in the damages that would be available for the same infringement. Many observers believe the use of juries in the US to assess the amount of damages creates greater uncertainty and leads to higher damages awards.		

Accounting of Profits See CETA Article 21(a)(ii). This article requires no change to Canadian law.	In an accounting of profits, the amount owing to the patentee is measured by the infringer's gain, rather than by the patentee's loss. This remedy is discretionary; a patentee may request an accounting of profits instead of damages. The amount owing under an accounting of profits may be more or less than the amount that would be owing under an award of damages, depending on the circumstances.	Accounting of infringer's profits not available	Accounting of infringer's profits not available
Permanent Injunction See CETA Article 20.1. This article requires no change to Canadian law.	A permanent injunction prevents the defendant from using the invention going forward without the permission of the patentee. In some cases a patentee that is granted a permanent injunction will refuse to allow the defendant to use the invention. This is commonly the case when the patentee is actively making and selling the patented product. In other cases, the patentee will agree to license the invention to the defendant, and the injunction serves as bargaining leverage. In Canada and the US, a permanent injunction is discretionary, in the sense that the court may refuse to grant a permanent injunction to a successful patentee, but the courts have historically granted permanent injunctions more or less routinely.		
	A permanent injunction is in principle discretionary, but to date the courts have almost always granted a permanent injunction to a successful patentee.	A permanent injunction is in principle discretionary, but until the 2006 decision of the US Supreme Court in *eBay v MercExchange* the courts almost always granted a permanent injunction to a successful patentee. In *eBay* the US Supreme Court held that permanent injunctions should not be granted routinely. Since then, permanent injunctions are still granted most of the time, but they are no longer routine and may be refused, particularly when the patentee is a non-practicing entity.	The availability of permanent injunctions is determined based on the national case law in patent matters of the respective member states of the European Union. The EU Enforcement Direction 2004/48/EC, Art 11, requires member states to provide that a permanent injunction may issue against an infringer.
Interlocutory Injunction	An interlocutory injunction may be sought by a patentee on an expedited basis in order to preserve the position of the parties pending trial, by preventing the defendant from carrying out what the patentee claims is an infringement of its patent. An interlocutory injunction is only effective until the rights of the parties are determined at trial. In all jurisdictions, the grant of an interlocutory injunction is discretionary.		
	While the grant of an interlocutory injunction is discretionary in principle, the test used by the Federal Courts is stringent, and in practice it is very difficult for a patentee to obtain an interlocutory injunction.	The grant of an interlocutory injunction is discretionary. Such injunctions are not granted routinely, but may be available on the facts of a particular case.	The grant of an interlocutory injunction is governed by national law and the ease with which an interlocutory injunction may be obtained by a patentee varies by jurisdiction. However, the Court of Justice of the EU (Europe's highest court in interpreting harmonized laws among member states) has confirmed that national courts in Europe are not prevented from granting pan-European preliminary injunctions[5]. A preliminary injunction to block infringing acts throughout Europe may be obtained in single proceeding;

			it is no longer necessary that all defendants be domiciled in the territory where the court resides, nor do the alleging infringing acts need to be committed in specific territory.
Border Measures See CETA Article 25.2 requiring import and export border measures respecting IPRs. Canadian law would require change to provide for export related border measures. On our information, it may be that this provision would apply only to trade-marks and copyright. If it applies to patents as well, Canadian law would have to be changed to provide for border measures in respect of patented goods. See CETA Article 25.1 in which Europe proposes that competent authorities may request a right holder to supply information that may reasonably be expected to be within the right holder's knowledge to assist the competent authorities in taking the border measures. Canada proposes to delete this section. See CETA Article 25.2 describing the proposed scope of measures.	Border measures refer to procedures that allow goods that infringe patents or other IP rights to be detained at the border by customs officials.		
	Canada has no export related border measures, and no patent-related border measures. The *Trade-marks Act* provides that when wares illegally bearing a registered trade-mark have been imported into Canada but are not yet released, or are about to be distributed in Canada, a court may order that the wares be detained pending a determination of the legality of that importation or distribution. The court may also prohibit future importation of infringing goods. These provisions may apply to pharmaceuticals when the packaging and pill shape and/or colour are trade-marked. The *Copyright Act* also has some import border measures, but these are not relevant to pharmaceuticals.	The US International Trade Commission (ITC) has the power to prohibit the importation of infringing goods. The ITC will normally grant an order banning the importation of the goods in question if a determination is made that they infringe a valid patent. This applies to IPRs of all types, including patents.	European Council Regulation 1383/ 2003 provides for the suspensive detention of imported goods by the customs authorities to see if they infringe IP rights. When customs officials have sufficient grounds for suspecting that goods infringe an intellectual property right they may temporarily detain the goods and inform the IP rights holder. The IP rights holder may then bring an action for a declaration that its rights have been infringed. The initial detention is an administrative proceeding before the customs authorities. The action for a declaration that the IP rights have been infringed is normally brought before a court. This procedure applies to IP rights of all types, including patents.

Exhaustion See CETA Article 4. The proposed article would not require any change to Canadian law.	The law of exhaustion limits the ability of an IP owner to control resale of products embodying IPRs once the product has been put on the market by the IP owner in an authorized sale. Conditions related to territorial exclusivity, and particularly "grey marketing" are often at issue in exhaustion cases, but the doctrine applies to any type of restriction that may be enforced by an IP action against a subsequent purchaser.		
	Exhaustion of rights is not codified in any of the IP Acts, and relevant case law is sparse. It is doubtful whether there is a general principle of exhaustion that applies to all types of intellectual property. At the time of purchase, the purchaser of a patented product acquires an implied license to use or resell that product. Unless otherwise stipulated in the licence, a licensee is generally entitled to pass to a purchaser the right to use or resell the patented article without fear of infringing the patent. If the sale is outside Canada but the vendor holds the Canadian patent rights and there is no limitation imposed at the time of sale as to the Canadian rights, than those Canadian rights can be passed on to the purchaser under an implied license. Rights based on the common law tort of passing off are generally exhausted by a first authorized sale. The owner of a registered trade-mark cannot use its rights under the *Trade-Marks Act* to prevent importation of goods that were released by the IP owner in a foreign market if the IP owner owns both the Canadian and foreign rights; but if the Canadian rights and foreign rights are owned by different companies, the Canadian rights owner might be able to prevent importation of goods released abroad by the foreign rights owner. It appears that in some circumstances copyright law may be used effectively to prevent importation of goods released on a foreign market.	An authorized sale generally exhausts the rights of an IP owner, but there are limits on this general rule. Under the first sale doctrine, an authorized and unrestricted sale in the US of a patented product exhausts the patent rights in the US over that particular product. Thus, a patentee cannot later sue a customer who uses the product in an infringing manner. The US Federal Circuit Court of Appeals has held that a conditional sale does not exhaust the patentee's rights. However, this doctrine was restrictively applied by the US Supreme Court decision in *Quanta Computer v LG Electronics*. In the context of trade-marks, the exhaustion doctrine will not apply to the importation of foreign goods if there are material differences between the foreign goods and those authorized for domestic sale. There is no pan-NAFTA exhaustion.	The sale of a patented product by the patentee or by an authorized party (licensee) anywhere in an EU member state exhausts the national patents in EU member states, but the sale of a patented product by a patentee/authorized party (licensee) outside the EU does not exhaust the patent rights in EU member states.

Litigation procedure			
Jury trials	Patent litigation in the Federal Court is heard before a judge alone.	US law is unique in that patent infringement trials may be heard before a judge and jury. The judge instructs the jury as to the law, but the jury makes the final determination, subject to a limited review by the courts.	Patent litigation heard before a judge alone.
Bifurcation	Assessment of monetary awards (damages or accounting of profits) may be bifurcated into a separate hearing, on the view that it is not necessary to hear evidence on damages if there is no infringement, and even if the defendant is found to infringe, parties are often able to settle damages once liability has been determined. All other issues – claim construction, infringement, validity and entitlement to any discretionary remedy (injunctive relief or an accounting), are determined in the first proceeding.	In US litigation, there is often an initial hearing dealing only with claim construction (so-called "Markman" hearing), on the view that claim construction is often important or determinative of infringement and validity and parties often settle after claim construction is determined. This hearing is before a judge alone.	In German litigation, infringement and validity actions are bifurcated and heard by separate courts. The infringement action is normally faster, with the result that the defendant may be held liable for having infringed a patent which may ultimately be held to be invalid. This is generally considered to be unfavourable to the defendant, which will often want to challenge the validity of the patent as part of its defence. Germany is currently an important jurisdiction for patent litigation in Europe. It is not clear what the procedure will be if the new Unified Patent Court is implemented.
Prosecution issues	Patents are not granted automatically; they must be examined to ensure that only patents that comply with the law are granted. "Patent prosecution" refers to the exchange between the patent office and the inventor or their patent agent during which the patent examiner verifies that the application discloses and claims a patentable invention.		
Initiation of examination	Applicant must request examination	Examination starts automatically	Applicant must request examination

Accelerated examination	There are three ways to expedite examination:[6] A. Special Order- CIPO may advance out of its routine order the examination of an application on the request of any person, on payment of the fee if failure to advance the application is likely to prejudice that person's rights. B. There is the option of requesting expedited examination for "green" technologies. C. The Patent Prosecution Highway (PPH) program allows a Canadian patent application that meets certain criteria to be advanced out of turn for examination if there is at least one corresponding application in a foreign patent office with which Canada has a PPH agreement, if the Canadian application has one or more claims that are substantially the same as claims that were found to be allowable by the other Patent Office.	Accelerated examination may be requested, however it is relatively costly. Applicant can file petition based on applicant's age or health to expedite examination. The Patent Prosecution Highway (PPH) is an option and a PPH agreement exists with Canada.	Accelerated examination can be requested in writing. The Patent Prosecution Highway (PPH) is another option, but PPH agreements only exist with the United States and Japan.
Disclosure requirements	Must respond in good faith to any office action, but there is no ongoing positive obligation to disclose relevant prior art publications to the Patent Office.	Duty of Candor - ongoing positive obligation to disclose relevant prior art publications to the Patent Office.	Applicants are required to file information on previous prior art searches of priority applications.
Application	Any legal entity may be an applicant. Agent can sign the application.	The applicants must be the inventors. Inventors must execute and file a declaration. The *America Invents Act* will allow filings by non-inventors if they have shown they have a sufficient proprietary interest. Furthermore, inventor-declarations only have to be submitted before an application is allowed.	Any legal entity may be an applicant. Agent can sign the application.
Maintenance Fees	Due annually, beginning on the second anniversary.	Due only three times during the patent term. (only if granted).	For applications, the first renewal fee is due two years after filing the application, and subsequent renewal fees are due annually. For granted patents, yearly renewal fees are payable in each country where the patent is validated.[7]

Administrative challenges to patents	A third party can challenge an application by submitting prior art or a protest against the granting of a patent. After a patent has been issued a request for re-examination may be filed at the patent office, in which prior art is filed. This may be done by anybody any time during the life of the patent. No *inter partes* opposition procedure. Limited evidence can be submitted in reexamination proceedings.	Third Party Submissions of prior art are allowed with time limitations. (2 months after publication - 6 months in 2012, AIA) After a patent has been issued a request for re-examination may be filed at the patent office. This may be done by anybody any time during the life of the patent. The *America Invents Act* will create an *inter partes* opposition system. However some observers are of the view that litigation will remain a better option.	Formal *inter partes* opposition procedure at the EPO. This can avoid the need to litigate in multiple European jurisdictions.

	Canada	United States	Europe
II. Pharma-Biotech Issues			
Statutory Subject Matter			
Higher life forms	Higher life forms (i.e. a genetically modified mouse) are not patentable. However, the cells of higher life forms are patentable. The net result is that a genetically modified higher life form will be patentable, so long as the cells are claimed rather than the plant or animal itself.	Higher life forms are patentable.	The EPC Art 53 says that "plant or animal varieties or essentially biological processes for the production of plants or animals" are not patentable. The EPO Board of Appeal has interpreted this to mean that higher life forms that are the product of traditional cross-breeding are not patentable, but higher life forms that are the product of genetic engineering are patentable.
Methods of medical treatment	At one time the *Patent Act* provided that substances intended for medicine could not be claimed as compounds as such. The Supreme Court, relying on this provision, held that methods of medical or surgical treatment are also unpatentable.[8] That section of the Act was repealed in 1987, with effect from 1991. There have been few cases since then on whether methods of medical treatment are patentable, in light of the repeal of this provision. One Federal Court decision has held that methods of medical treatment involving professional skill (in particular, a drug dosage regime) are unpatentable.[9] Claims framed in terms of "use" rather than a method of treatment may be allowable.	Methods of surgical and medical treatment are patentable. However, medical practitioners have a specific defence and cannot be sued for using patented methods.[10]	Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human and animal body are not patentable. However, these exclusions are interpreted narrowly by the EPO and Enlarged Board of Appeals. The EPO Enlarged Board of Appeal has held that a dosage regime is patentable.[11] The Enlarged Board of Appeal has held that new methods during examination phase to collect clinical data of a human being or animal may be patentable inventions, and that methods cannot be excluded merely due to fact they include steps that depend of participation of a medical or veterinary practitioner.[12]
Stem cells	In its *Harvard Mouse* decision, the Supreme Court of Canada has said that "human life is not patentable." It is not clear whether this means that stem cells are not patentable. The Patent Office	There is no particular subject matter restriction affecting stem cells.	The EPO Enlarged Board of Appeal has held that stem cells which could only be obtained from a method which involved the destruction of human embryos are not patentable. Beyond this basic principle,

	position is that pluripotent stem cells are patent eligible, while totipotent stem cells are not[13].		individual European jurisdictions may have different positions on the types of stem cells which may be patent eligible.
Personalized medicine	Personalized medicine turns on the ability to identify the ways in which different individuals respond differently to the same therapeutic drug or medical treatment. Advances in personalized medicine often involve determining a correlation between the genetic or metabolic characteristics of an individual and the response to a drug or treatment. Patentability of such advances has been the subject of recent US cases, including the 2012 decision of the US Supreme Court in *Mayo v Prometheus*. Personalized medicine is not directly affected by any CETA provisions, but it may become an issue in the future.		
Utility	The utility requirement (framed as "industrial applicability" in European law), affects how early in the research process a patent may be granted. That is, can an inventor get a patent on a new compound simply if it shows some possibility for therapeutic use, or is it necessary to establish that it is likely to be useful through in vitro tests, animal tests, or human tests? The timing of when a patent may be granted is very important in competitive industries, such as pharmaceuticals, as the innovators want to get a patent as early as possible in order to establish their position against rivals, but not so early that the patent is invalid. In the US, the function of controlling how soon an invention may be patented is also controlled in part by what is known as the "written description" requirement.		
Standard for assessing utility	In Canada, the required utility is normally determined by "the promise of the patent." That is, the patent itself is examined to see what utility the inventor has promised, and the patent will be invalid if that utility is not established. This makes utility more difficult to establish in Canada than in the US or Europe.	Utility is a patentability criterion. A specific and substantial (non-frivolous) credible utility must be disclosed in the patent application.	Utility (called industrial applicability) is a patentability criterion. The patent must disclose a practical application, so that the ensuing monopoly can be expected to lead to some commercial or concrete benefit. A merely speculative use will not suffice
Post-filing evidence	Evidence post-dating the filing date, such as the result of subsequent clinical trials, may not be used to establish utility. This makes utility more difficult to establish in Canada than in the US or Europe.	Post-filing data is liberally admitted into the record and widely used during prosecution in response to utility objections.	Post-filing data is liberally admitted into the record and widely used during prosecution in response to utility objections.
Disclosure of evidence supporting utility	When utility is based on demonstrated utility, which is to say that the utility of the drug has been established as of the claim date, the evidence establishing that utility need not be disclosed in the patent itself. However, when utility is based on a sound prediction of utility, which is to say that the information available to the patentee does not go far enough to establish demonstrated utility, the evidence supporting the sound prediction must be disclosed in the patent itself.	Generally, a stated utility (unsupported by data) is sufficient. Evidence supporting utility need not be disclosed in the patent itself.	Generally, a stated utility (unsupported by data) is sufficient. Evidence supporting utility need not be disclosed in the patent itself.

Double patenting	An applicant is only entitled to a single patent on an invention. Double patenting refers to an applicant having two patents/applications having claims with identical scope (co-terminous double patenting) or that are not patentably distinct (obviousness type double patenting). The result is the impermissible extension of patent term beyond the 20 year term allowed for a single patent filing. Consequently, one of the filings would be objected to in prosecution because of the other, or if both were to be issued as patents, this could be used as grounds to challenge their validity. A patentee cannot disclaim the extra period of protection to rescue the later expiring filing from invalidity.	A Terminal Disclaimer may be filed in response to an obviousness type double patenting objection. This means that the applicant would disclaim rights in the later expiring patent, so that the statutory 20 year term of protection would not be exceeded and both filings could be allowed to issue as valid patents. This provides a straightforward manner to deal with double patenting objections and reduces the risk of patent invalidity based on allegation of double patenting.	Unlike in Canada and US, where double patenting objections are commonly raised during prosecution and are frequently a basis for challenging the validity of granted patents, double patenting has very limited application under European patent practice and double patenting is not a basis to oppose a patent in European opposition proceedings.

	Canada	United States	Europe
III. Drug Patent Regulatory Issues[14]	In order to market a drug, the drug maker must obtain market authorization by satisfying the health regulatory authorities of the safety and efficacy of the drug. In Canada this is known as a Notice of Compliance. When a drug is first marketed these regulatory requirements must be satisfied by submitting the results of clinical trials that will normally have been carried out by the drug company that is seeking to market the drug. In Canada, this is known as a New Drug Submission (NDS). Carrying out the necessary clinical trials is often a lengthy and expensive process.		
Patent term extension See Article 9.2 of CETA	The effective period of patent monopoly for pharmaceutical products may be less than the 20 year patent term due to the time spent conducting clinical trials. The data obtained from such clinical trials must be filed with the regulator prior to marketing authorization. Because the patent term runs for 20 years from the date of filing of the patent, the time taken for the clinical trials and the subsequent regulatory approval process may reduce the effective term of the patent as compared with what would be available in the absence of these regulatory requirements. Patent term extension is intended to extend the patent term to compensate for a lengthy regulatory approval process.		
Duration See Article 9.2 of CETA, in which Europe proposes patent term extensions of a maximum of 5 years plus an additional 6 months if pediatric studies have been carried out. This is the same as currently available in Europe. This would require a change to Canadian law.	No patent term extension. Canada is the only country in the G8 that does not offer any form of patent term extension.	Maximum extension of 5 years, but the total remaining patent term from the date of marketing approval (patent term + extension) cannot exceed 14 years. The extension is calculated as: • 50% of the period of clinical trials, calculated as follows: period beginning [the later of i) filing of the IND or ii) grant of the relevant patent] and ending with the filing of the NDA; **plus** • 100% of the regulatory review period, calculated as follows: period beginning with date of filing of the NDA and ending with date of NDA approval	A patent term extension in Europe is called a Supplemental Protection Certificate (SPC). For a single patent per product, a maximum extension of 5 years is available, but the total patent term (patent term + SPC) cannot exceed 15 years. Duration is the time between the date of first regulatory approval in an EU Member State and date of filing of the patent application, less five years, with a maximum duration of five years. Extension must be applied for on a country by country basis.
Data protection/exclusivity See CETA Article 10	Data Exclusivity is a period of time following market authorization of a medicine during which a generic manufacturer cannot rely in whole or in part on the clinical data generated by the innovator and submitted to regulatory authorities. Data exclusivity rewards the investment made in the development of confidential clinical and non-clinical information for regulatory purposes. It is required under TRIPs Agreement, Article 39.3: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use." When a drug company seeks to rely on another's safety and efficacy data (e.g. to introduce a generic version of an approved drug, or to introduce a biosimilar version of an approved drug), it may conduct its own clinical trials and submit the results in order to establish the safety and efficacy of its product or submit an "abbreviated submission" referring to previously generated data by the other		

	sponsor. Data exclusivity may also be important when the patent expires soon after the drug is launched, perhaps because of regulatory delay.		
Pediatric exclusivity/pediatric extension See Article 10 where Canada has indicated the value of providing added incentives for development of pediatric indications	Several countries offer a data exclusivity incentive to drug developers to carry the further expense of performing clinical trials in pediatric populations. These incentives were introduced to address a shortage of safety and efficacy studies specifically generated for this sub-population.		
Duration See Article 10 of CETA where Europe proposes that data exclusivity be increased in Canada to 10 years with a maximum of 11 years as is currently provided for in Europe	Data protection in Canada is restricted to an "innovative drug", a drug that contains a medicine not previously approved in Canada. Canada does not provide data protection for any subsequent new use of a previously approved drug. The maximum term of data protection is: 6+2+0.5 = 8.5 years, which is broken down as: no abbreviated submission for 6 years; no regulatory approval for additional 2 years; and an additional 6 months for submissions that include pediatric studies.	In the US, data protection is calculated differently for biological drugs versus small molecule drugs. Traditional pharmaceuticals are small molecules which are normally produced by chemical synthesis. Biological drugs are large complex molecules made through the metabolic activity of living organism, which typically involves cloning, selection of a suitable cell line, fermentation and purification. (The US offers a shorter term of data protection for small molecule drugs, i.e. 5 yrs, than for biologic drugs, i.e. 12 years, based on policy rationale that development of a biologic drug is far more complex and costly than for small molecule drugs such that a longer minimum term of market exclusivity is required for biologic drugs to provide an adequate incentive to innovate in this field.) For biological drugs, the standard term of data protection is 12 years. The six-month period for pediatric studies may be added to either the maximum patent term or the maximum term of data protection, such that the maximum data protection for biologics may be 12.5 years. For small molecule drugs, the maximum is: 5 + 3 +0.5 = 8.5, which is broken down as: no abbreviated submission for 5 years, unless patents are challenged (patents cannot be challenged within first 4 years of drug approval); an additional 3 years data exclusivity for significant changes (new indication); and an additional 6 months for submissions that include pediatric studies.	In Europe, the maximum is: 8+2+1= 11 years, which is broken down as: no abbreviated submission for 8 years; no regulatory approval for an additional 2 years; and an additional 1 year data exclusivity for significant changes (new indication). Sponsors must conduct pediatric studies, where applicable, and the incentive is built into the base term (8+2).

Orphan drugs (drugs for diseases affecting a relatively small proportion of the population)	Canada does not provide a guaranteed term of data protection for orphan drugs. If eligible, orphan drugs benefit from same 8.5 year data protection as generally available in Canada.	Orphan drugs get 7 year term of orphan drug exclusivity.	Orphan drugs benefit from same 10 year data protection as generally available in EU.
Patent linkage See CETA Article 10 bis (discussed below). Note that there is no provision for Europe to have a patent linkage regime.	Some countries (including Canada and the US), link market authorization of a generic drug to the patent status of innovative comparator referred to in an abbreviated submission, ("patent linkage"). When a brand/innovator obtains marketing authorization, it may list certain types of patents relating to the drug on the Patent Register. If a generic wishes to obtain approval by filing an abbreviated submission, it must also address patents listed against that drug on the Patent Register. The generic does not have to address the listed patents if it generates its own clinical data and files an NDS instead of an abbreviated submission but this is expensive and in practice is not done. The generic addresses the patents by agreeing that it will not launch until all the listed patents have expired, or by asserting that the listed patents are invalid or will not be infringed. If it asserts that the listed patents are invalid or will not be infringed, then determination of the patent issues is made in accelerated proceedings prior to grant of the market authorization. In Canada the linkage proceedings are governed by the Patented Medicine (Notice of Compliance) Regulations, known as PM(NOC) regulations. The Canadian linkage system is analogous to an interlocutory injunction. In the absence of the linkage mechanism, as in Europe, when a generic launches a drug before the expiry of a patent that the brand believes is relevant, the brand/innovator may sue for infringement. The brand may then apply for an interlocutory injunction, which will prevent the generic from launching until the litigation is complete or the parties have settled. The application for an interlocutory injunction will be heard relatively quickly, and the effect, if granted, is similar to the statutory stay. Europe does not link market authorization to the patent system, but because the effect is analogous to an interlocutory injunction, in the following chart, the US and Canadian linkage systems will be compared to an interlocutory injunction in Europe.		
Automatic stay?	Yes, if proceedings started by patentee within 45 days	Yes, if proceedings started within specified number of days	No. Interlocutory injunction is determined on the basis of a test that varies by country.
Length of stay	24 months or until determination of the proceedings	30 months or until determination of the proceedings	Until trial
Finality	PM(NOC) proceedings are intended to be speedy in nature, and use a simplified procedure as compared with patent infringement litigation (i.e., the hearings are done on a paper record with no live witnesses). A finding in PM(NOC) proceedings that the patent in question is not valid is only effective as between the parties, and does not result in a declaration that the patent is invalid. If a generic is successful in having the patent declared invalid in the PM(NOC) proceeding, and consequently obtains a NOC and launches a generic version of the drug, the patentee may, and normally does, bring an infringement action as soon as the generic	The US linkage proceedings are considered to be in an infringement action. If the generic is successful and the patent is declared invalid, it is invalid for all purposes.	Interlocutory injunction proceedings are intended to be speedy in nature, and use a simplified procedure as compared with patent infringement litigation. The interlocutory injunction remains in place until the validity of the patent is determined at trial.

	launches. Because the evidence will be different, the result in the infringement action may be different from the result in the PM(NOC) proceedings.		
Appeals See CETA Article 10 bis where Europe proposes that where there are patent linkage mechanisms, it shall ensure that patent holders and the manufacturers of generic medicines are treated in a fair and equitable way, including their respective rights of appeal. This would require a change to Canadian law to provide for an effective appeal right of appeal by a patentee from adverse decision in an NOC proceeding in the Federal Court. Alternatively, Canada could comply with the proposed Art 10bis by repealing the patent linkage mechanism implemented in the NOC Regulations. The Canadian system would then be the same as the European system.	In principle, either the generic or the patentee may appeal an adverse holding in PM(NOC) proceedings to the Federal Court of Appeal. However, if the generic is successful, the Minister of Health will normally issue the NOC almost immediately. Once the NOC has been issued, the Federal Court of Appeal will refuse to hear the appeal on the basis that it is moot. The patentee's recourse is to bring an infringement action against the generic, from which there is a right of appeal.	Because the linkage proceeding is considered to be an infringement action, the unsuccessful party may appeal, as it would an infringement action.	An adverse result in an interlocutory injunction proceeding may in principle be appealed by either party. Some observers suggest that such appeals are rarely successful.
First generic exclusivity	No exclusivity for first generic.	The first generic to successfully obtain marketing authorization under this procedure is entitled to 180 days of exclusivity before other generics are permitted to enter the market. This is to provide the first generic with an incentive to undertake the expense of the proceedings.	No exclusivity for first generic.

Subsequent-Entry Biologics (SEB), bio-similars, Follow-On Biologics (FOB) These terms are equivalent	As noted above, traditional pharmaceuticals are small molecules which are normally produced by chemical synthesis. Biological drugs are large complex molecules made through the metabolic activity of living organism, which typically involves cloning, selection of a suitable cell line, fermentation and purification. Subsequent-Entry Biologics (SEB), bio-similars, follow-on biologics are equivalent terms meaning a "generic-like version" of a biologic drug (see above: Data Protection - US). The basis for an abbreviated regulatory approval is a comparison of the active ingredient of a candidate generic or SEB with a reference product. Because biologics are produced by living organisms, the end-product is sensitive to small changes in the characteristics of those organisms or the conditions in which they are grown. More detailed chemistry and manufacturing information is therefore necessary to assess the purity and quality of a biologic drug. Canada, Europe and the US all agree that the only way to assess safety and efficacy of a SEB is to conduct some original non-clinical and clinical tests. They also agree that if a SEB is demonstrated to be highly similar to a previously approved reference product, the data generated in regards to the reference product may be relevant in evaluating the SEB.		
Legislative framework	Canada considers that no specific new legislation is necessary to provide a regulatory framework to assess SEB submissions. Health Canada published a guidance document for companies wishing to file a submission for a SEB (March 2010). Market authorization in Canada for a first SEB was granted in April 2009 to Sandoz Canada (Novartis) for OMNITROPE, recombinant somatropin (human growth hormone).	US FDA considered itself not to have authority to grant market authorization for SEB absent enabling legislation from US Congress. The *Biologics Price Competition and Innovation Act* was signed into law by President Obama on March 23, 2010. The FDA has begun implementing regulations but there is no track-record of SEB/FOB approvals under the new Act.	The EMA settled a general guideline for SEBs in 2005; it also issued a series of further class-specific guidelines which were used to grant market approval for several SEB products in each class. Guidelines relate to quality, non-clinical, and immunogenicity issues. It is believed that the EMA granted market authorization in Europe for SEBs for follow-on recombinant human insulin, growth hormone, granulocyte colony-stimulating factor (GCSF), epoetin (EPO), and mAb SEBs.
Reference Product (RP)	Canada, Europe and the US all agree that the RP must have obtained market authorization on the basis of a complete regulatory data package (quality, non-clinical and clinical data) package. Europe, Canada and the US indicate that the reference product should have the same route of administration, dosage form, and strength as the candidate SEB. The US law further requires that the reference product and candidate SEB share the same mechanism of action.		
	Canada allows for a biologic drug that is not the version authorized for sale in Canada to be used as a RP in some circumstances.	No foreign RP permitted. US law requires use of a single reference product licensed under the normal US biologics licensure pathway.	RP must have received market authorization in Europe. Data generated from comparability studies with a version of the reference product authorized outside the European Community may only provide supportive information.

Patent enforcement	Canada and the US have specialized enforcement mechanisms for protecting patent rights relevant to biologic medicines. Under these mechanisms, market authorization of a SEB is linked to resolution of certain patent rights relevant to the RP.		
	CA enforcement mechanism, the Patented Medicines (Notice of Compliance) Regulations applies to enforce patent rights related to both biologic medicines and small molecule drugs. (see above) 1. Not all patents that may be relevant to marketing the SEB are eligible for listing on the register in regard to a reference product. For example, patent rights directed to manufacturing processes, cell lines and expression systems are not listable or enforceable under this mechanism. 2. CA system focuses more on the active ingredient per se.	US provides a patent enforcement mechanism tailored more specifically to biologic medicines. It is quite different from the patent listing system used for new chemical entity (NCE) drugs (see above). 1. Enhanced disclosure to the sponsor of a SEB of the process of making the RP. The sponsor of a SEB would disclose information including a detailed description of the follow-on biologic, its methods of manufacture, and the materials used in the manufacture of the product. The holder of market authorization of the reference product would, in turn, provide notice of all relevant patents and a statement explaining why the patent rights would be infringed by the follow-on biologic. The law requires the RP patent holder and the sponsor to confer in identifying and prioritizing potentially relevant patents for litigation. 2. Enforcement of a broader range of patents, i.e. process and platform patents, cell lines and expression systems.	As noted above, Europe does not have a similar patent enforcement mechanism; holders of patent rights in Europe generally rely on preliminary injunctions, the availability of which varies according to national law of member states, to settle patent disputes prior to launch of a generic version of a patented drug.

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