



Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement (TPP): Comparative Analysis of the United States' Intellectual Property Proposal and Laws of New Zealand¹

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Issue	Leaked U.S. TPP Proposal ³	New Zealand Patent Act 1953	Analysis
<p>Patent Law Treaty (2000)</p>	<p>Article 1.5. Each Party shall make all reasonable efforts to ratify or accede to the following agreements by the date of entry into force of the Agreement:</p> <p>(a) Patent Law Treaty (2000); and</p>	<p>New Zealand is not a contracting party to the Patent Law Treaty (PLT).</p> <p><i>New Zealand's Ministry of Foreign Affairs and Trade has stated that New Zealand does not belong to and is not seeking to join the PLT.</i>⁴</p>	<p>The PLT is a treaty of the World Intellectual Property Organization (WIPO). It harmonizes formal procedures involved in national and regional patent applications. The requirements regarding the form of application are quite low. It has been subject to criticism for favouring patent applicants and increasing the burden on national patent offices.</p> <p>The PLT recognizes a presumption of validity on the part of internationally-issued patents and would reduce New Zealand's flexibility to independently evaluate Patent Cooperation Treaty-processed patent applications.</p>

³ The September US text is available at: <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf>, The February US text is available at: <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>.

⁴ See New Zealand's Ministry of Foreign Affairs and Trade, Trans-Pacific Partnership Negotiations – Intellectual Property Stakeholder Update, 18 May 2011, available at <http://www.mfat.govt.nz/downloads/trade-agreement/transpacific/IP%20Stakeholder%20Update.pdf>.

<p>Patentability Requirements</p>	<p>Article 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.</p> <p>FN15: For the purposes of this Article, 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 claimed invention.</p>	<p>Section 1 <i>Invention</i> means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture; and includes an alleged invention.</p> <p><i>In order to be patentable, an invention needs to meet two criteria:</i></p> <ul style="list-style-type: none"> ▪ <i>it must be new, and</i> ▪ <i>should be a "manner of manufacture."</i> <p>The definition of invention also includes the Statute of Monopolies proviso that inventions “should not be contrary to law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade or generally inconvenient”.⁵ The Court of Appeal has only applied this proviso in regard to excluding methods of medical treatment.⁶</p> <p><i>New Zealand adopts a two-step test</i></p>	<p>While this provision, which mirrors in part Article 27 of the TRIPS Agreement, would not require TPP parties to change their laws, it illustrates the differences in patent standards between the negotiating countries, and is helpful in understanding how the subsequent U.S.-proposed provisions and patent standards would change the laws of New Zealand and other TPP countries.</p> <p>In U.S. law and practice, ‘usefulness’ is interpreted broadly to cover any application, utility, or improvement over existing products and/or techniques. “Capable of industrial application” tends to be a more precise concept, leading to higher quality patents. In some cases, treating “capable of industrial application” as synonymous with “useful” can lower patentability standards.</p> <p>Under the TRIPS Agreement and this proposed article, countries may treat the terms as synonymous, but are not required to do so.</p>
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⁵ See, *Pfizer Inc. v. Commissioner of Patents* [2005] 1 NZLR 362.

⁶ “...[W]e cannot realistically shut our eyes to the possibility that in the language of the Statute of Monopolies the change sought by the respondent might result in “raising prices at home” or be “generally inconvenient.” *Wellcome Foundation Ltd. v. Commissioner of Patents* [1983] NZLR 385 (CA).

		<p><i>for determining patentability. Anything that does not fall within the definition of invention is not regarded as patentable, even though it satisfies all the other criteria of patentability. Novelty is considered at the second step of the patentability test, which needs to be satisfied before a patent application is granted.</i></p> <p><i>There is no requirement for inventive step and/or industrial application in the Patents Act because New Zealand does not fully examine patents when they are applied for, but only if there is pre-grant opposition or post-grant revocation action. Patents can be challenged before grant (opposition) or after grant (revocation) on the basis of lack of inventive step or industrial application/utility (the latter only in revocation).</i></p> <p><i>The Patents Bill 2008 (the Bill 2008) before Parliament introduces substantive examination of the application upon request of the applicant. This will consequently introduce inventive step and industrial application requirement to the patent system.</i></p>	
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<p>Industrial Application v. Utility</p>	<p>Article 8.12. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.</p>	<p><i>There is no industrial application or utility requirement under the Patent Act. But the case law requires inventions to be industrially applicable⁷.</i></p> <p><i>An invention is required to amount to a “manner of manufacture” in order to be patentable in New Zealand. This test does not explicitly require an invention to be capable of industrial application or useful. Patents, however, may be revoked on the basis of non-usefulness. (Section 41 (1) (g)). New Zealand law adopts the UK approach and requires the actual contribution of an invention to be useful in order to</i></p>	<p>The TPP provision aims to impose the U.S. test of specific, substantial and credible utility.</p> <p>Although New Zealand Law does not explicitly require industrial application, the Intellectual Property Office of New Zealand (IPONZ) requires inventions to be able to be made or used in some kind of industry. However, the notion of specific, substantial and credible utility is broad enough to cover inventions without industrial application and does not require the actual contribution of the invention to be useful. It facilitates patentability of activities and enhances the patentability of research tools. Accordingly, any invention that has a practical application and that produces useful and specific results</p>

⁷ See, *Wellcome Foundation Ltd. v. Commissioner of Patents* [1983] NZLR 385 (CA).

		<p><i>satisfy patentability criteria.</i></p>	<p>satisfies the utility requirements.</p> <p>In the U.S., the utility requirement is linked to the written description and enablement requirement. The patent applicant has to demonstrate utility in the patent application. Secondly, this disclosure must instruct those who read the patent how to use and make the invention and the best mode of practicing it.</p> <p>It is highly ambiguous whether this legal transplantation of the U.S. utility test would operate in exactly the same way in New Zealand.</p>
<p>Best Mode Disclosure</p>	<p>Article 8.10 Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue examination, as of the filing date.</p>	<p>Section 10 (3) Every complete specification (a) Shall particularly describe the invention and the method by which it is to be performed; and (b) Shall disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and (c) Shall end with a claim or claims defining the scope of the invention claimed.</p> <p><i>The Patent Act requires patent applicants to disclose the best-known method of performing the invention.</i></p>	<p>Under U.S. law, the patent applicant is required to disclose not only how to make and use the invention but also the best mode of making and practicing the invention. Best mode disclosure is an important public policy safeguard, which ensures the public has sufficient information about the invention and that others be able to compete fairly with the patentee after patent expiration.</p> <p>The TPP proposal requires the patent applicant to provide information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date. This provision, however, skips the 'best mode' requirement.</p>

			<p>Accordingly, a description based merely on hypothesized results would be sufficient as there is no requirement for a working example.</p> <p>Best mode disclosure is important to ensuring the quality of patents that are granted, particularly in biotechnology and biopharmaceuticals. Best mode disclosure facilitates effective competition, for example, by helping the public as well as generics or biosimilar manufacturers learn and glean the best possible information about the patented invention. Disclosure of best mode should be included to the text.</p>
<p>Protection of New Forms, Uses, or Methods of Using a Known Product</p>	<p>Article 8.1. 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.</p>	<p><i>Methods of medical treatment of human beings to prevent or cure disease are not considered a manner of manufacture.</i></p> <p><i>Nevertheless, first medical use claims, in the form of 'substance X for use as a Y-treating agent,' are accepted by the Intellectual Property Office of New Zealand (IPONZ).</i></p> <p><i>The IPONZ also allows second or subsequent use claims presented in the "Swiss-type" format. Swiss-type claims are allowable for novel compounds or compositions. They</i></p>	<p>Patents for new forms, uses, and methods of using known medicines can enable patent 'evergreening' and, particularly when enhanced therapeutic efficacy is not required, can lead to unwarranted extensions of pharmaceutical monopolies.</p> <p>The current practice in New Zealand is to provide patent protection to new medical uses and new therapeutic effects of known products. However, patent applicants are required to comply with patent claim drafting requirements of the IPONZ. In practical terms, this requirement sets some limits on the patenting of new uses of known medicines.</p>

		<p><i>have also been permitted where the compound is known and the use is known, but there is a novel dosage. The IPONZ offers an extensive set of guidelines setting out the criteria for what is acceptable and what is not in this regard.</i></p>	<p>The U.S. proposal would provide greater flexibility to pharmaceutical companies when they draft their patent claims. Rather than claiming Swiss-type use or method claims, pharmaceutical companies would be able to freely file patent applications for new uses, new methods of preparation and methods of use or treatment (when read in conjunction with Article 8.2 eliminating exclusions from patentability, as discussed further below) without being subject to any restrictions.</p> <p>Additionally, this provision would prevent New Zealand from changing patent standards regarding patentability of new uses and forms, by locking New Zealand into the status quo. If New Zealand ever considers it necessary to provide an express and detailed statutory presumption against patentability of derivatives, such as that found in the India Amended Patent Act (2005) Section 3(d), it would be unable to do so due to its obligations under the TPP.</p>
<p>Exclusions from Patentability</p>	<p>Article 8.2. Each Party shall make patents available for inventions for the following:</p> <ul style="list-style-type: none"> (a) plants and animals, and (b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals 	<p><i>New Zealand does not provide patents for methods of medical treatments. The Patent Act does not include an explicit exclusion for these methods. However, it is established by case law that methods are excluded from</i></p>	<p>The TRIPS Agreement allows countries to exclude diagnostic, therapeutic and surgical methods from patentability (Article 27.3).</p> <p>New Zealand excludes diagnostic and treatment methods from patent protection on the basis that such claims do not meet the definition of invention. New Zealand</p>

		<p><i>patentability. This exclusion rests on policy grounds and aims to ensure medical practitioners are not subject to restraints when treating patients.⁸</i></p> <p><i>IPONZ does not grant patents for methods for the treatment of humans by therapy or surgery, or methods of diagnosis that are performed directly on the human body, are not accepted by the IPONZ⁹. The Bill 2008 proposes an express exclusion for methods of treatment.</i></p> <p><i>This exclusion, however, does not extend to patents for second medical uses of known compounds drafted in the Swiss-type format, e.g. use of compound X in the manufacture of a medicament for the treatment of a particular medical condition.</i></p>	<p>considered the issue in 2004 and concluded that the benefits of such patents would not outweigh the costs.¹⁰ However, the IPONZ allows patents for second and subsequent medical use claims drafted in the Swiss-type format.</p> <p>As explained above, Article 8.1 provides patent protection to new uses and method claims. Article 8.2 makes methods of treatment for the human (or animal) body eligible subject matter for patents. Article 8.12 interprets industrial application in a broad sense and seeks specific, substantial and credible utility to satisfy industrial application requirements. When read together, these three Articles, in effect, lengthen patent protection for older pharmaceuticals by facilitating patents for methods of treatment and minor variations on known products. The U.S. proposal would lead to broader pharmaceutical patenting and more low-quality patents in New Zealand.</p> <p>The new fields of health technology, e.g. biotechnology and genetic science, make</p>
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⁶ "...I respectfully think, a deep-seated sense that the art of the physician or the surgeon in alleviating human suffering does not belong in the area of economic endeavour or trade and commerce. Cooke J., Wellcome Foundation Ltd. v. Commissioner of Patents [1983] NZLR 385 (CA), Pharmaceutical Management Agency Ltd. v. Commissioner of Patents [2000] 2 NZLR 529 and Pfizer Inc. v Commissioner of Patents [2005] 1 NZLR 362.

⁹ New Zealand allows patents for diagnostic methods where those methods are not practiced directly on the human body, but, for example, are practised on cells that are removed from the human body for genetic testing. This is found in IPONZ guidelines on the scope of the exclusion of diagnostic methods.

¹⁰ See Wikileaks cable; Revised Patent Law Won't Help Drug Industry In New Zealand- 28.10.2004, available at: <http://www.cablegatesearch.net/cable.php?id=04WELLINGTON900>.

			<p>extensive use of method claims in their patent applications. Such methods and procedures are usually carried out on the human (or animal) body or are somehow related to treatment of the human (or animal) body. The expansion of patent protection to diagnostic, therapeutic and surgical methods for the treatment of human beings (and animals) makes patent protection available for higher life forms and human biological materials.</p> <p>The TRIPS 27.3 patentability exception is an important flexibility recognized by many countries for moral and ethical reasons, and to prevent hospitals and medical professionals from paying royalties on the standard of care.</p> <p>While the U.S. proposes to bind countries to its standard through the TPP, it has omitted the essential safeguards and balancing features of its own law. While U.S. law authorizes patents for surgical methods, it also prevents medical practitioners from being sued for patent infringement in the course of medical activity (35 USC 287 (c)). (Nevertheless, other groups including universities, medical education companies, and hospitals can be held liable for involuntary infringement.)</p> <p>Adopting the U.S. proposal, without adopting appropriate safeguards, opens up prospects</p>
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			<p>for additional costs imposed on New Zealand's healthcare system. It is possible that hospitals could be required to obtain licenses for patented treatments that they offer, and doctors could be asked to pay royalties for the patented diagnostic, therapeutic and surgical methods they use.</p>
<p>'Bolar'-type Exemption</p>	<p>Article 8.5. Consistent with paragraph [4] (<i>patent exceptions and limitations</i>), each Party shall permit third persons to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product in that Party, and shall further provide that any product produced under such authority shall not be made, used, or sold in its territory other than for purposes related to generating such information to support an application for meeting marketing approval requirements of</p>	<p>Section 68B. It is not an infringement of a patent for a person to make, use, exercise, or vend the invention concerned solely for uses reasonably related to the development and submission of information required under New Zealand law or the law of any other country that regulates the manufacture, construction, use or sale of any product.</p> <p><i>The provision allows for the production, sale or use of a patented product, without the patentee's</i></p>	<p>Bolar-type (regulatory) exemptions support non-commercial research uses of patented inventions and facilitate immediate entry of products into the market following patent expiration.</p> <p>New Zealand's regulatory review exception – also known as the springboarding provision – is modeled on a similar provision in the Canadian Patents Act. The Disputes Settlement body of the World Trade Organization established that this springboarding provision is consistent with Article 30 of the TRIPS Agreement.</p>

	<p>that Party. If the Party permits exportation of such a product, the Party shall provide that the product shall only be exported outside its territory for purposes of generating information to support an application for meeting marketing approval requirements of that Party.</p>	<p><i>permission, for uses “reasonably related” to the development and submission of information required for the purpose of obtaining marketing approval either in New Zealand or overseas.</i></p> <p><i>The scope of New Zealand’s exception is quite broad, and is not limited to pharmaceutical products. There is no limitation on which products could be used or tested for the purpose of obtaining marketing approval in any country – not only New Zealand.</i></p>	<p>The scope of the springboarding provision in New Zealand law is quite broad in that it applies to any product that requires regulatory approval, including chemical, veterinary and agricultural products.</p> <p>The TPP exemption is narrow in scope – it only applies to pharmaceutical products. But the Bolar exemption in U.S. law is broader than the U.S. proposal to the TPP. The scope of the exemption in U.S. law covers not only pharmaceutical products but also medical devices <i>Eli Lilly and Co. v. Medtronic, Inc.</i>, 872 F.2d 402).</p> <p>The U.S. draft apparently also limits the scope of the exemption for obtaining marketing approval to the territory of the Party. Unlike New Zealand law, the U.S. proposal would seemingly prevent the exemption from being used to generate information abroad for marketing approval at home.</p>
<p>Patent Term Adjustment (For Patent Prosecution Period)</p>	<p>Article 8.6.</p> <p>(a) Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in</p>	<p>Section 30 (3) The term of every patent shall be 20 years from the date of the patent.</p> <p><i>The Patent Act contains no provision addressing patent term restoration or</i></p>	<p>The patent system in New Zealand rests on the policy that a limited term monopoly will be granted as an incentive to innovation.¹¹</p> <p>Patent term adjustments (typically called extensions) allow patent owners to postpone</p>

¹¹ *Pharmaceutical Management Agency Ltd v. Commissioner of Patents*[2000] 2 NZLR 529, 532 (CA) per Gault J. See also *Pfizer Inc. v. Commissioner of Patents* [2005] 1 NZLR 362 per Hammond J.

	<p>the granting of the patent. For purposes of this subparagraph, an unreasonable delay at least shall include a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party, or two years after a request for examination of the application has been made, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays.</p>	<p><i>adjustment. There is no obligation to grant patent term extension for unreasonable delays in patent examination and granting.</i></p>	<p>patent expiry. This further delays market entry of competing generic drugs and restricts access to affordable medicines.</p> <p>The U.S. TPP proposal introduces general patent term adjustments applying to all fields of technology including pharmaceutical products and processes. The U.S. proposal defines unreasonable delay as the later of four years from the date of filing or two years after an examination request.</p> <p>Patent term adjustments allow patent owners to postpone patent expiry. A patent term adjustment that is applicable to pharmaceutical products and processes would further delay market entry of competing generic drugs, restricting access to affordable medicines in New Zealand.</p>
<p>Patent Term Adjustment (For Regulatory Review Period)</p>	<p>Article 8.6 (c) Each Party, at the request of the patent owner, shall make available an adjustment of the patent term of a patent which covers a new pharmaceutical product or a patent that covers a method of making or using a pharmaceutical product, to compensate that patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.</p>	<p><i>No patent term extension is available in New Zealand to compensate for unreasonable regulatory delays in the approval process.</i></p> <p><i>Following the introduction of the springboarding provision in 2002, patent term extension for pharmaceuticals was also discussed in New Zealand. It was concluded that patent term extensions provide no benefit to New Zealand. They further delay the market entry of</i></p>	<p>Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines. The TPP requires that Parties make patent term extensions available for perceived delays in the regulatory approval process.</p> <p>There are no extensions of patent terms in New Zealand. The U.S. TPP proposal introduces patent term adjustments not only for patents covering new pharmaceutical products but also for patents that cover</p>

	<p>(d) In implementing subparagraph 6(c), a Party may:</p> <ul style="list-style-type: none"> i. limit the applicability of subparagraph 6(c) to a single patent term adjustment for each new pharmaceutical product that is being reviewed for marketing approval; ii. require the basis for the adjustment to be the first marketing approval granted to the new pharmaceutical product in that Party; and iii. limit the period of the adjustment to no more than 5 years. 	<p><i>generic drugs and result in a higher cost of medicines. No link has been found between patent term extensions and increased levels of foreign pharmaceutical investment in New Zealand</i>¹².</p>	<p>methods of making or using pharmaceutical products (this should be read in conjunction with Article 8.1, which makes patent protection available for new uses, methods and forms of known products).</p> <p>Article 6 provides some flexibility for determining limitations on the period of patent term extensions. These limitations are similar to, though not entirely the same as; those found in the U.S. Patent Act, i.e., a party may limit extensions to one per pharmaceutical product.</p>
<p>Third-Party Opposition</p>	<p>Article 8.7. (...) Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available before the grant of the patent.</p>	<p>Section 21 (1) At any time within the period prescribed by subsection (2) of this section any person interested may give notice to the Commissioner of opposition to the grant of the patent on any of the following grounds: (...)</p> <p>(2) Every such notice shall be given</p>	<p>Pre-grant opposition is a safeguard against patent abuse, improvidently granted patents and unwarranted pharmaceutical monopolies. Pre-grant opposition supports appropriate generic competition and access to medicines. The U.S. proposal would eliminate pre-grant opposition in TPP countries.¹³</p> <p>Pre-grant opposition allows third parties to</p>

¹² See, Pharmaceutical Patent Term in New Zealand, Review of the Patents Act 1953, Discussion Paper, Ministry of Economic Development, June 2003, available at: <http://www.med.govt.nz/business/intellectual-property/pdf-docs-library/patents/review-of-patents-act/patents-act-1953-pharmaceutical-patent-terms-pdf>.

¹³ For further discussion of the U.S. strategy to eliminate patent pre-grant opposition, see Public Citizen, HealthGAP, I-MAK and Third World Network, "Analysis of the Leaked U.S. Paper on Eliminating Patent Pre-Grant Opposition," available at <http://www.citizen.org/documents/analysis-of-leaked-US-paper-on-eliminating-pregrant-opposition.pdf>.

		<p>within 3 months from the date of the publication of the complete specification under this act. (...) Section 42 (1) At any time within 12 months after the sealing of a patent, any person interested who did not oppose the grant of the patent may apply to the Commissioner for an order revoking the patent on any one or more of the grounds upon which the grant of the patent could have been opposed:</p> <p><i>The New Zealand patent system allows for both pre-grant and post-grant opposition. Once a patent application is published, any interested third party can oppose it within 3 months from the publication. The main grounds for opposition include lack of novelty, obviousness, non-patentable subject matter, and insufficiency.</i></p> <p><i>Interested third parties who did not oppose the grant of patent can apply to the Patent Commissioner to revoke the patent within 12 months after the grant. This is known as belated opposition. Additionally, third parties can seek revocation of a patent through proceedings at the High Court (Section 41).</i></p>	<p>formally oppose a patent application by submitting information and analysis to patent examiners under an adversarial administrative process. Pre-grant opposition helps improve patent quality and the accuracy of patent claims. This process helps prevent pharmaceutical monopolies based on meritless patents that contribute little to innovation but greatly to price.</p> <p>The absence of pre-grant opposition would make patent examination less informed and would likely increase the number of post-grant cases before the courts. Costs associated with the patent opposition system could rise significantly. This would create market uncertainty for generics firms, and lead to low-quality patents and unjustified drug monopolies until post-grant challenges could reach a successful conclusion.</p>
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<p>Protection of Test Data Submitted for Marketing Approval</p>	<p>Article 9.2.</p> <p>(a) If a Party requires or permits, as a condition for granting marketing approval for a new pharmaceutical product, the submission of information concerning the safety or efficacy of the product, the origination of which involves a considerable effort, the Party shall not, without the consent of a person previously submitting such safety or efficacy information to obtain marketing approval in the territory of the Party, authorize a third person to market a same or similar product based on:</p> <ul style="list-style-type: none"> (i) the safety or efficacy information previously submitted in support of the marketing approval; or (ii) evidence of the existence of the marketing approval, <p>for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.</p> <p>(...)</p> <p>(c) If a Party requires or permits, as a condition of granting marketing approval for a pharmaceutical</p>	<p>Medicines Act, Section 23B. Where the Minister receives, or received not more than 5 years before the commencement date, an innovative medicine application and confidential supporting information, the Minister, during the protected period in relation to that confidential supporting information,—</p> <ul style="list-style-type: none"> (a) Shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the Minister; and (b) Shall not use that confidential supporting information for the purposes of determining whether to grant any other application. <p><i>New Zealand provides five years data exclusivity for “innovative medicine applications”. This refers to a medicine where an active ingredient has not previously been approved as an active ingredient of a medicine. The protection does not extend to new uses, new formulations or indications of known active ingredients.</i></p>	<p>Data exclusivity prevents regulatory authorities from relying on established data regarding drug safety and efficacy to register generic medicines. Data exclusivity delays generic market entry and is inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals.</p> <p>New Zealand law provides data exclusivity for five years, but the protection only applies to new active ingredients and undisclosed confidential supporting information.</p> <p>The leaked U.S. TPP proposal requires data exclusivity for new pharmaceutical products. This provision provides “at least” five years of data exclusivity for safety and efficacy information submitted in support of marketing approval, even if it is disclosed and in the public domain. The September 2011 text also introduces “at least three years” additional data exclusivity for submission of new clinical information on new uses or indications for existing pharmaceutical products. Products that are considered the same as or similar to the reference product are also prevented from relying on its protected data.</p> <p>Data exclusivity provisions are also inconsistent with medical ethical standards</p>
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	<p>product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of the pharmaceutical product containing the previously approved chemical entity, other than information related to bioequivalency, the Party shall not, without the consent of a person previously submitting such new clinical information to obtain marketing approval in the territory of the Party, authorize a third person to market a same or a similar product based on:</p> <ul style="list-style-type: none"> (i) the new clinical information previously submitted in support of the marketing approval; or (ii) evidence of the existence of the marketing approval that was based on the new clinical information, <p>for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party.</p>		<p>against duplicating tests on humans or vertebrate animals.</p> <p>The U.S. may also seek data exclusivity for biologics (biotech medicines). This would represent a change to New Zealand law with potentially dramatic financial consequences.</p>
<p>Patent Linkage</p>	<p>Article 9.5. Where a Party requires or permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that</p>	<p><i>New Zealand law contains no provision that links the patent system to the marketing approval process.</i></p>	<p>Patent linkage is a regulatory mechanism that links drug marketing approval to patent status. Under patent linkage, even spurious patents may function as barriers to generic drug registration. Patent linkage can facilitate abuse since the financial benefits to patent</p>

	<p>information or on evidence concerning safety or efficacy information for a product that was previously approved, such as evidence of prior marketing approval in another territory, each Party shall:</p> <p>(a) provide a transparent and effective system to:</p> <ul style="list-style-type: none"> (i) identify a patent or patents covering an approved pharmaceutical product or its approved method of use; and (ii) provide notice to a patent holder of the identity of another person who intends to market, during the term of the identified patent or patents, a product that is the same as, or similar to, the approved pharmaceutical product referenced in subparagraph 5(a)(i). <p>(b) unless such other person agrees to defer the marketing of the product until after the expiration of an identified patent, ensure that a patent holder may seek, prior to granting of marketing approval to an allegedly infringing product, available remedies by providing:</p> <ul style="list-style-type: none"> (i) an automatic delay of the grant of marketing approval that remains in place for a period of time designed to ensure sufficient opportunity to adjudicate disputes concerning the validity or infringement of 		<p>holders of deterring generic market entry may outweigh risks of penalties.</p> <p>The U.S. TPP proposal requires countries to provide a mechanism to identify patents covering an approved pharmaceutical product or its approved method of use. The U.S. draft introduces a notification system for patent holders, an automatic stay of marketing approval and measures to block allegedly infringing products for the duration of the patent.</p> <p>It is not clear from the wording of the provision under what conditions a product would be considered “similar to” an approved pharmaceutical product and trigger an obligation to notify a patent holder. This provision could facilitate patent holder harassment of potential competitors.</p>
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	<p>allegedly infringed patents; and</p> <p>(ii) judicial or administrative procedures, including effective provisional measures, to allow for the timely adjudication of disputes concerning the validity or infringement of an allegedly infringed patent.</p> <p>(c) if such other person's product has been found to infringe a valid patent identified pursuant to subparagraph (a), provide measures that operate to prohibit the unauthorized marketing of that product prior to the expiration of the patent.</p> <p>(d) when a Party delays the grant of marketing approval consistent with subparagraph 5(b)(i), provide an effective reward, consistent with the provisions of this Agreement, for the successful challenge of the validity or applicability of the patent.</p>		
<p>Judicial and Administrative Presumption of Patent Validity</p>	<p>Article 10.2. (---) In civil and administrative proceedings involving patents, each Party shall provide for a rebuttable presumption that a patent is valid, and shall provide that each claim of a patent is presumed valid independently of the validity of the other claims.</p>	<p><i>There is no expressed judicial or administrative presumption of patent validity in New Zealand.</i></p>	<p>The judicial and administrative presumption of patent validity gives rise to costly and one-sided court procedures, and makes it harder to challenge unwarranted patents.</p> <p>The U.S. TPP proposal requires each claim of a patent to be presumed valid independently of the validity of the other claims. When read in</p>

			<p>conjunction with eliminating pre-grant opposition and the provision on patent linkage, this provision threatens the integrity of the New Zealand patent system and overrides current reform proposals designed to improve the quality of patents.</p> <p>This presumption was only introduced into the U.S. Patents Act in 1952. Since then, there has been overwhelming evidence that patent quality is not high enough to justify its continuation under U.S. patent law.</p>
<p>Compensation of Damages for IP Infringement</p>	<p>Article 12.3. Each party shall provide that b) in determining damages for infringement of intellectual property rights, its judicial authorities shall consider, <i>inter alia</i>, the value of the infringed good or service, measured</p>	<p><i>Statutory remedies for infringement include injunctions, award of damages or account of profits. Where the loss to the plaintiff is difficult to quantify, an account of profit is awarded.</i></p>	<p>The U.S. draft proposes use of suggested retail price or other legitimate measures of value submitted by the right holder. This provision strongly favors the interests of the right holders. A suggested retail price is a hypothetical price. This retail price must necessarily be greater than the damage</p>

	<p>by the suggested retail price or other legitimate measure of value submitted by the right holder</p>	<p><i>In case of innocent infringement, the infringer may avoid the need to pay damages or account for the profits made (Section 68 (1)).</i></p>	<p>suffered by the right holder. Calculations submitted by a right holder may turn out to be inflated or otherwise inaccurate and higher than existing retail prices. This would lead to an unrealistic determination of damages, which would empower right holders in court settlements and discourage people from defending cases where there is uncertainty.</p> <p>It is essential to keep the compensatory approach based on proportionality. The courts should filter claims and calculation of damages should be determined on a case-by-case basis.</p>
<p>Ex-officio Border Measures</p>	<p>Article 14.4. Each Party shall provide that its competent authorities may initiate border measures <i>ex officio</i> with respect to imported, exported, or in-</p>	<p><i>In New Zealand, border measures are provided only in the Copyright Act 1994 (Part 7) and Trademarks Act 2002 (Subpart 3) for right</i></p>	<p>Special border measures that are too broad in scope or fail to include adequate safeguards can lead to customs error or right holder abuse, including the customs seizure</p>

	<p>transit merchandise, or merchandise in free trade zones, that is suspected of being counterfeit or confusingly similar trademark goods, or pirated copyright goods.</p>	<p><i>owners.</i></p> <p><i>Customs can enforce border measures only when goods have been imported and are in control of Customs- not when goods are merely in transit.</i></p> <p><i>Customs-related measures can only be taken upon the request of right owners. Neither the Copyright Act nor the Trademark Act provide for Customs to take ex-officio action against infringing goods.</i></p>	<p>of generic medicines.¹⁴</p> <p>The U.S. proposal would broaden the scope of special, pre-emptive border measures to include suspected civil trademark infringement, a standard that does not contribute to public safety but does risk wrongly detaining generic medicines, which may usefully communicate their bioequivalence to consumers through similar packaging.</p> <p>The U.S. proposal would extend special border measures authority to products exported from or merely in transit through New Zealand- not only those destined for New Zealand's market.</p>
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¹⁴ For further discussion of special border measure standards, see Public Citizen, Comments to the European Commission on Customs Regulation 1383/2003, May 25, 2010, available at: <http://citizen.org/Page.aspx?pid=3458>.