SCHOOL OF LAW
CASE WESTERN RESERVE UNIVERSITY

Canada-United States Law Journal

Volume 40 | Issue 1 Article 8

2016

Promise Utility Doctrine and Compatibility Doctrine Under NAFTA: Expropriation and Chapter 11 Considerations

Freedom-Kai Phillips

PROMISE UTILITY DOCTRINE AND COMPATIBILITY UNDER NAFTA: EXPROPRIATION AND CHAPTER 11 CONSIDERATIONS

*Freedom-Kai Phillips**

ABSTRACT: The 2013 filing by Eli Lilly of a notice of arbitration under Chapter 11 of NAFTA relating to the application of the promise utility doctrine in Canadian jurisprudence brought to light latent tensions relating to domestic patent standards, perceived barriers to innovation, and international investment standards. This paper explores applicable NAFTA obligations and patent regimes in an effort to identify points of convergence and divergence, and argues that the promise utility doctrine while differentiated on procedural grounds domestically has significant substantive alignment across jurisdictions, and is overall consistent with the standard of treatment established under NAFTA. The promise utility doctrine, which is grounded in a harmonized view of the theoretical underpinnings of the patent bargain, progressively articulates the enduring need to maintain highly-specific disclosure standards to support sound patent practices, maintain ongoing innovation, and dissuade otherwise speculative or suppressive practices.

TABLE OF CONTENTS

I. INTRODUCTION

Invalidation of a patent for lack of utility based on the promise utility doctrine identifies important questions pertaining to the compatibility of such an approach with pre-existing trade obligations, particularly those established under the North American Free Trade Agreement ("NAFTA").[1] In 2013, Eli Lilly & Company ("Eli Lilly") filed a notice of arbitration under NAFTA claiming that the recent invalidation of two patents based on the application of the promise doctrine was tantamount to direct or indirect expropriation.[2] This paper will explore the validity and compatibility of the promise utility doctrine as articulated in Canadian jurisprudence with investor-state protections as established under NAFTA through a review of the current Chapter 11 dispute initiated by Eli Lilly over the invalidation of patents for Zyprexa and Strattera. First, a brief outline of the Chapter 11 dispute will be offered as background, including both patent and procedural historical summaries. Second, applicable investor-state protections as established under NAFTA are summarized. Third, patent standards across NAFTA jurisdictions are discussed with particular emphasis on highlighting the evolution and alignment of the promise utility doctrine. Fourth, the promise utility doctrine is critically appraised to assess consistency with established NAFTA obligations, with specific emphasis on direct and in-direct expropriation. Finally, concluding thoughts are offered, highlighting points of convergence and divergence. The promise utility doctrine marks a progressive evolution in the assessment of a patent's utility which, while initially raising *prima facie* concerns over incompatibility, remains consistent with NAFTA obligations.

While consistent with the position of the Government of Canada in the dispute overall, it is on the scope of Intellectual Property ("IP") system alignment and the applicability of the police powers exception to expropriation where our positions slightly diverge. I assert that IP regimes under NAFTA jurisdictions are far more harmonized theoretically and substantively than previously recognized, with mechanical deviation relating to the operative components of the regime to address a utility inquiry acknowledged. I also note the unique market circumstances which have fostered the promise utility doctrine. Furthermore, the fair, non-arbitrary and transparent judicial application of the patent bargain through the promise utility doctrine fits within the police powers exception to expropriation. International law cannot be utilized to justify dilution of the patent system to the point where speculative patent practices are encouraged or accepted. The promise utility doctrine marks an inflection point for patent interpretation in an age of unbounded innovation, an evolutionary step rightly grounded in a harmonized view of the theoretical underpinnings of the patent bargain, and a progressive approach to patent interpretation which benefits the global patent community.

---

[1] North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 639.

[2] Eli Lilly & Co. v. Canada, Notice of Arbitration, UNCT/14/12, (Sept. 12, 2013).

II. BACKGROUND

This section aims to briefly outline the factual elements which underlay the dispute as background. First, the historical backdrop underlying the successful granting of Canadian Patent No. 2,041,113 for "Zyprexa," and Canadian Patent No. 2,209,735 for "Strattera" is summarized. Second, the procedural history relating to challenges to the aforementioned patents is discussed. The evidentiary basis supporting and the procedural steps which led to the invalidation of the Zyprexa and Strattera patents provides valuable context and insight to consider in light of the Investor-State expectation of fair and equitable treatment ("FET").

A. Patent History: Zyprexa and Strattera

Founded in 1876, Eli Lilly has progressively established a long history of conducting innovative research and development in the pharmaceutical sector,[3] and like other cost-intensive sectors, is highly dependent upon the use of IP rights system, particularly patents, to recuperate the significant investment associated with drug development.[4] Zyprexa (olanzapine), a thienobenzodiazepine derivative commercially used in the treatment of schizophrenia, was first developed, clinically tested, and patented in the United Kingdom,[5] leading to patent applications in a total of eighty-one jurisdictions including Canada and the United States.[6] Canadian Patent No. 2,041,113 (the "113 patent") for Zyprexa was filed April 24, 1991 and issued July 14, 1998, and covers the pharmaceutical application of 2-methyl-thieno-benzodiazepine to treat disorders to the central nervous system, schizophrenia, schizophreniform disease, acute mania, and mild anxiety states.[7] The 113 patent was a "selection patent," insomuch as it selected specific compounds based on a previous originating ("genus") patent, Canadian Patent No. 1,075,687 (the "687 patent"), which covered a widespread set of compounds based on the common three-ring molecular structure "thienobenzodiazepine."[8] United States Patent No. 5,229,382 was filed May 22, 1992,[9] and issued July 20, 1993, and carries with it an equivalent scope.[10] Following regulatory approval, Zyprexa entered the market in 1996 and gained widespread application for treatment of schizophrenia.[11]

Strattera (atomoxetine), an early non-stimulant based treatment for attention-deficit hyperactivity disorder ("ADHD"), grew out of early research on the use of atomoxetine for treatment of depression.[12] United States Patent No. 5,658,590

---

[3] James H. Madison, *Manufacturing Pharmaceuticals: Eli Lilly and Company, 1876-1948*, 18 BUSINESS AND ECONOMIC HISTORY 72, 72-78 (1989).

[4] Paul Grootendorst, *Patents and Other Incentives for Pharmaceutical Innovation*, *in* Elsevier Encyclopedia of Health Economics (2014).

[5] U.K., Patent No. 9009229.7 (issued April 25, 1990).

[6] Eli Lilly & Co. v. Canada, Claimant's Memorial UNCT/14/2, Lilly Obtaining Patent, ¶ 84-85 (Sept. 29, 2014).

[7] Canada, Patent No. 02,041,113 (issued April 24, 1991).

[8] Eli Lilly Canada Inc. v. Novopharm Ltd., [2011] F.C. 1288, ¶ 1-2.

[9] U.S., Patent No. 07/690,143 (issued April 23, 1991).

[10] U.S., Patent No. 5,229,382, (issued July 20, 1993).

[11] Canada, Claimant's Memorial, *supra* note 6, ¶ 92.

[12] *Id.* ¶ 118.

was filed on January 11, 1995,[13] and issued August 19, 1997, and covers the "method of use" of tomoxetine for treatment of ADHD and impulse-type disorders.[14] Filed under the Patent Cooperation Treaty on January 4, 1996 and published July 18, 1996, Canadian Patent No. 2,209,735 (the "735 patent") was issued October 1, 2002.[15] Principal evidence for the filing was a supportive seven-week study conducted by Massachusetts General Hospital ("MGH"), which was provided to Health Canada to support approval but was not disclosed as a component of the patent application.[16]

B. Procedural History: Zyprexa and Strattera

Both Zyprexa and Strattera follow a common procedural path resulting from a challenge filed by a generic drug manufacturer, with the former being in retort to claims of infringement and the latter being pre-emptive in nature. In the case of the 113 patent for Zyprexa (olanzapine), Eli Lilly claimed Novopharm, a Canadian generic drug manufacturer, was infringing the aforementioned patent in the production of "novo-olanzapine." This question was first addressed by Justice O'Reilly at the Federal Court [trial judgment], with his judgment of October 5, 2009. Justice O'Reilly dismissed the claim of infringement on the basis that the 113 patent was not a valid selection patent, as at the time of patent, Eli Lilly had not included sufficient information to demonstrate or soundly predict the utility described in the patent application, and that olanzapine was encompassed in the previous 687 patent which lasted between 1980 to 1997.[17] The trial judgment was overturned by the Federal Court of Appeal ("FCA") in the decision delivered by Justice Layden-Stevenson on July 21, 2010 [FCA Judgment], which held that Justice O'Reilly erred in his interpretive approach towards selection patents, and therefore, had fatally undermined the analysis of utility.[18] As such, the questions of utility and the sufficiency of disclosure in the patent were remitted back to the Federal Court for proper consideration.[19]

In the follow-up decision by the Federal Court [second trial judgment],[20] Justice O'Reilly applied the guidance provided by the FCA in considering utility which included: (i) affirmation that a selection patent must provide a "substantial advantage," have all selected members exhibit the advantageous qualities, and have the selection be made on the basis of this "quality of a special character,"[21] and (ii) that while a mere scintilla of utility is generally sufficient, where a patent makes an explicit promise, the principle consideration must shift to "whether the

---

[13] U.S., Patent No. 08/371,341 (issued Jan. 11, 1995).

[14] U.S., Patent No. 5,658,590 (issued Aug. 19, 1997).

[15] Canada, Patent No. 2,209,735 (issued July 18, 1996).

[16] Canada, Notice of Arbitration, *supra* note 2, ¶ 50; Canada, Claimant's Memorial, *supra* note 6, ¶ 119.

[17] Eli Lilly Canada Inc. v. Novopharm Ltd., [2009] FC 1018, ¶ 154.

[18] Eli Lilly Canada Inc v Novopharm Ltd, [2010] FCA 197, ¶ 108-109.

[19] *Id.* ¶ 124.

[20] Eli Lilly Canada Inc v Novopharm Ltd., [2011] FC 1288.

[21] *Id.* ¶ 81-82; Novopharm, *supra* note 18, ¶ 19-22; *Sanofi-Synthelabo Canada Inc v Apotex Inc*, [2008] SCC 61, [2008] 3 SCR 265 [*Sanofi-Synthelabo*], relying on *Re I.G. Farbenindustrie AG's Patents* (1930), 47 RPC 289 (Ch D).

invention does what the patent promises it will do."[22] As a selection patent, the 113 patent was required to demonstrate utility in terms of fulfillment of a specific promise of a substantial advantage based on a sound prediction of that promise at the time the patent was filed.[23] Justice O'Reilly constituted the promise of the 113 patent to be that "olanzapine treats schizophrenia patients. . . in a markedly superior fashion with a better side-effects profile than other known antipsychotics." Citing insufficient clinical studies and lack of a sound line of reasoning, Justice O'Reilly concluded that indeed, the 113 patent did not meet this promise at the time of patent.[24] Leave was denied to both the FCA, and the Supreme Court of Canada ("SCC").[25]

Regarding the 735 patent for Strattera (atomoxetine), Teva Canada Limited (formerly Novopharm) initiated an action in Federal Court seeking a finding of invalidity for the aforementioned patent,[26] opening the door for commercial sales of the generic equivalent. On September 14, 2010, Justice Barnes first recognized the 735 patent to be indicating an "inventive new use" of a known compound.[27] Second, in considering utility, he cited *Consolboard*, *AZT* and the reasoning articulated in the consideration of the 113 patent for Zypreza; he reiterated that utility is a product of the invention doing what is claimed for a person skilled in the art, based on sufficient evidence or sound prediction at the time of patent.[28] Utility is identified as not equitable with the treatment working for all patients, nor working for only a single patient. As noted by Justice Barnes, disclosure must sufficiently demonstrate effectiveness or support a sound prediction.[29] Where a sound prediction is made, he cited *AZT*, indicating that disclosure in the patent must include both "factual data" and the articulated "line of reasoning" underlying the sound prediction to satisfy the *quid pro quo* of the patent.[30] As the 735 patent was based on a sound prediction and as the MGH study had significant limitations,[31] and was neither disclosed nor referenced in the patent application, the patent was found to fail for "want of disclosure."[32] The trial findings were affirmed upon appeal, with the July 5, 2011 decision of the FCA reiterating that where the factual basis supporting the predicted utility is not

---

[22] Novopharm, [2011] FC 1288, ¶ 84; Novopharm, *supra* note 18, ¶ 74-77; Consolboard Inc v MacMillan Bloedel (Saskatchewan) Ltd, [1981] 1 S.C.R. 504, 56 C.P.R. (2d) 145; Pfizer Canada Inc v Canada (Minister of Health), [2008] FCA 108.

[23] Novopharm, [2011] FC 1288, ¶ 85-88; Novopharm, *supra* note 18, ¶ 78.

[24] Novopharm, [2011] FC 1288, ¶ 209-213, 273.

[25] Canada, Notice of Arbitration, *supra* note 2, ¶ 64; Eli Lilly Canada Inc. v. Novopharm Ltd., [2012] F.C.A. 232; Eli Lilly Canada Inc., et al. v. Novopharm Ltd., [2013] CanLII 26762 (SCC).

[26] Novopharm Ltd. v. Eli Lilly & Co., [2010] F.C. 915 [Can.].

[27] *Id.* ¶ 88.

[28] *Id.* ¶ 91-93; Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd., [1981] 1 S.C.R. 504, 56 C.P.R. (2d) 145, 524-526 (Can.); Novopharm, *supra* note 18; Apotex Inc. v. Wellcome Foundation Ltd., [2002] SCC 77, 21 C.P.R. (4th) 499, ¶ 70-71 (Can.).

[29] *Id.* ¶ 112, 116.

[30] *Id.* ¶ 117.

[31] *Id.* ¶ 102.

[32] *Id.* ¶ 94, 120.

disclosed, this is a breach of the public bargain underpinning patentability.[33] Leave to the SCC was denied on December 8, 2011.[34]

III. APPLICABLE OBLIGATIONS UNDER NAFTA

This section summarizes the applicable obligations of the Parties as established under NAFTA. First, the standard of treatment as established under Article 1105 is provided in conjunction with considerations relating to national treatment and most favoured nation ("MFN") under Articles 1102 and 1103 respectively. Second, expropriation under Article 1110 is discussed. Lastly, issues relating to IP rights as outlined in Articles 1701 and 1709 are summarized. The obligations under NAFTA establish a common framework for facilitation and regulation of trade based on principles of FET treatment.

A. Standard of Treatment

FET is a longstanding pillar of international economic law which has become the most frequently invoked standard in investor-state disputes.[35] Article 11 of NAFTA encompasses a collection of obligations relating to investment, which applies to investors and investments of another Party occurring in the territory of a Party.[36] First, each Party is obliged to accord "no less favourable treatment" to investors and investments of a foreign Party than is accorded to domestic counterparts in like circumstances.[37] Second, each Party is obliged to provide equivalent treatment to foreign investors and investments as is provided in like circumstances to any other nation – Party or non-Party.[38] The standards of national treatment in Article 1102 and MFN in Article 1103 are intended to create an even-handed standard of treatment governing investments made under the treaty,[39] which provides for no negative legislative or regulatory differentiation between foreign and domestic investment and discourages less-favourable treatment.[40] Third, Article 1105 establishes a minimum standard of treatment between Parties which ensures Parties are accorded FET and "protection and security" in accordance with international law.[41] Importantly for NAFTA Parties, the customary international legal norm of minimum standard of treatment is established as the minimum standard with FET and "protection and security" not indicating an increased standard;[42] this point provides clarity for interpretation of the relevant standard by tribunals.[43]

---

[33] Novopharm Ltd. v. Eli Lilly & Co., [2011] FCA 220, ¶ 51.

[34] Canada, Notice of Arbitration, *supra* note 2, ¶ 54.

[35] RUDOLF DOLZER AND CHRISTOPH SCHREUER, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW 119 (Oxford University Press, 2nd ed. 2008).

[36] NAFTA, *supra* note 1, Article 1101.

[37] *Id.* Article 1102.

[38] *Id.* Article 1103.

[39] *Id.* Article 1104.

[40] Dolzer & Schreuer, *supra* note 35, at 178, 186.

[41] NAFTA, *supra* note 1, Article 1105(1). [Minimum Standard of Treatment]

[42] NAFTA Free Trade Commission (FTC) Note of Interpretation (31 July 2001), online: Global Affairs Canada.

[43] Dolzer & Schreuer, *supra* note 35, at 126.

The standards of FET and "protection and security" under both codified and customary international law have evolved over time. While broad, the standard of FET finds early roots in considerations related to treatment of foreign aliens, which was outrageous, in bad faith, or illustrated an insufficiency of government reaction which reasonably illustrates an unacceptable departure from international standards.[44] More recently the standard has been noted to be evolving,[45] with a focus on a lack of due process and fairness,[46] which is considered conceptually without the "threshold limitation that the conduct complained of be egregious, outrageous, or shocking, or otherwise extraordinary."[47] Factors such as transparency, contractual compliance, procedural propriety, due process, good faith, and freedom from coercion have all been considered by tribunals in the evaluation of the standard of treatment.[48] Additionally, the standard of "protection and security" which initially applied to protection from physical threats has been contemporarily interpreted to apply to infringements on the rights of the investor through the application of law in the host state.[49] The focus conceptually has shifted beyond physical considerations to centralize generally on access to judicial remedy and diminishment of an investment.[50]

B. Expropriation

Expropriation, which sits at the crossroads of sovereignty and respect for rights acquired by foreign investors, generally involves interference by the host-State with a property interest to the detriment of the investor.[51] Article 1110(1) indicates that Parties are restricted from direct or indirect expropriation, or implementation of "measures tantamount to. . . expropriation," except for a public purpose, applied in a non-discriminatory manner, in accordance with due process, and with payment of equitable compensation.[52] Compensation, which is to reflect the fair market value of the investment at the time of expropriation, is to be paid "without delay," and shall be paid in a G7 currency or equivalent.[53] Article 1110(7) indicates explicitly that measures relating to the "issuance,

---

[44] Neer v Mexico, Opinion, US—Mexico General Claims Commission, 21 AJIL 555 (1927).

[45] ADF Group Inc. v USA, ICSID Case No. ARB(AF)/00/1, 18 FILJ 195, ¶ 179 (2003).

[46] Elettronica Sicula SpA (ELSI) (United States of America v Italy), Judgement, ICJ Reports 15 (1989).

[47] *Pope & Talbot v Canada*, Award on Merits (Phase 2), 122 ILR 352, ¶ 118 (2002); Dolzer & Schreuer, *supra* note 35, at 129.

[48] Dolzer & Schreuer, *supra* note 35, at 133-147; ROLAND KLÄGER, FAIR AND EQUITABLE TREATMENT' IN INTERNATIONAL INVESTMENT LAW 62-74 (Cambridge University Press 2013).

[49] Dolzer & Schreuer, *supra* note 35, at 149.

[50] *Id.* at 151-152, 162-166; CME v Czech Republic, Partial Award (13 September 2001), 9 ICSID Reports 121, ¶ 613; Lauder v Czech Republic, Award (3 September 2001), 9 ICSID Reports 66, ¶ 314.

[51] Andrew Newcombe & Lluís Paradell , Law and Practice of Investment Treaties: Standards of Treatment, (Netherlands: Kluwer Law International, 2009), at 321 [Newcombe & Paradell]; Dolzer & Schreuer, *supra* note 35 at 89.

[52] NAFTA, *supra* note 1, at Article 1110(1).

[53] *Id.* Article 1110(2-6); Andrea K Bjorklund, *NAFTA Chapter 11*, COMMENTARIES ON SELECTED MODEL INVESTMENT TREATIES (Oxford University Press, Chester Brown ed. 2013).

revocation, limitation, or creation" of IP rights which are consistent with Chapter 17 are exempted from consideration as expropriation.[54]

What amounts to direct or indirect expropriation is a matter of debate and divergence, with jurisprudence illustrating the inclusion of legislative, regulatory, or administrative actions,[55] "regulatory taking" and "creeping expropriation" which, through application of law, devalues an investment over time.[56] Tribunals have focused not just on deliberate actions, such as the revocation of a certificate or permit,[57] but also on "incidental interference" with the property which, in form or effect, neutralizes the economic benefit of the property,[58] or deprives the owner of a significant part of the "reasonably-to-be-expected economic benefit."[59] The standard of "substantial deprivation" in relation to a property right resulting in an economic loss has developed as a principal line of inquiry when considering indirect expropriation.[60] Finally, while the principles of public purpose, non-discrimination, due process, and compensation encapsulated in Article 1110(1) generally apply, where a non-discriminatory regulation, which supports a public purpose, is enacted in accordance with principles of due process and not in contravention to previously stated regulatory restraints, such normal exercises of regulatory power are suggested to be outside the scope of expropriation.[61]

C. Intellectual Property

Obligations relating to IP are addressed in Chapter 17 of NAFTA. Article 1701(1) establishes framework requirements on NAFTA Parties including: (i) providing adequate protection and enforcement of IP rights while ensuring IP measures are not trade inhibitors, and (ii) collectively actualizing previously established IP Conventions (Geneva 1971, Berne 1971, Paris 1967, and UPOV 1978, 1991).[62] Article 1702 empowers Parties to implement "more extensive" IP rights as an alternative, provided these measures remain consistent with the Agreement as a whole.[63] Article 1703 provides for the application of the principle of national treatment to the protection and enforcement of IP rights, restricts the implementation of formalities or preconditions to acquisition of IP rights (for instance, notice of copyright), and allows for derogation from this standard regarding judicial and administrative procedures (such as a requirement

---

[54] NAFTA, *supra* note 1, at Article 1110(7).

[55] JONATHAN BONNITCHA, SUBSTANTIVE PROTECTION UNDER INVESTMENT TREATIES: A LEGAL AND ECONOMIC ANALYSIS (Cambridge: Cambridge University Press, 2014), at 231-232; Newcombe & Paradell, *supra* note 51, at 326-327.

[56] Brown, *supra* note 53; Newcombe & Paradell, *supra* note 51, at 324-325.

[57] Goetz v Burundi, Award, 15 ICSID Review-FILJ 457 (2000) ¶ 124.

[58] CME v. Czech Republic, *supra* note 50.

[59] Metalclad v Mexico, Award, 5 ICSID Reports 209 (2002), ¶ 103.

[60] Pope & Talbot, *supra* note 47; Sempra Energy v. Argentina, Award, ICSID Case No. ARB/02/16, ¶ 284; Biwater v. Tanzani, Award, ICSID Case No. ARB/05/22 (2008); Bonnitcha, *supra* note 55, at 248-255.

[61] Methanex v. United States, Final Award (2005) ¶ 1-7; Saluka v. Czech Republic, Partial Award (2006) ¶ 255.

[62] NAFTA, *supra* note 1, Article 1701(1-2).

[63] *Id.* NAFTA, Article 1702.

to appoint a domestic agent) provided such derogation is consistent with the previously noted IP Conventions.[64]

Article 1709 is the principle substantive NAFTA provision relating to patents. Article 1709(1) requires Parties to make available patents for "all fields of technology," bearing the invention is "new," is the result of an "inventive step," and is "capable of industrial application," with Parties empowered to deem "inventive step" and "capable of industrial application" equivalent to "non-obvious" and "useful."[65] Article 1709(2) and (3) provide for exceptions to the minimum standard of patentability, particularly allowing Parties to exclude from patentability inventions which pose a serious harm to life, health or the environment (public order exception), as well as: surgical methods, non-microbial plants and animals, and biological processes for the production of non-microbial plants and animals.[66] Parties are further required to: (i) provide for patent protection for pharmaceuticals, chemicals, and agricultural products no later than January 1, 1992,[67] (ii) ensure that the acquisition of a patent provides for exclusive rights relating to the product or process, with the option to provide limited exceptions to such exclusive rights provided they are not unreasonably prejudicial,[68] and (iii) ensure patent rights may be exercised in a non-discriminatory manner with relation to the field, or geographic location for production of the technology.[69]

Article 1709(8) indicates that Parties may only revoke a patent where "grounds exist that would have justified a refusal to grant the patent," or where the issuance of a compulsory license has not remedied a lack of commercial exploitation.[70] Parties shall also permit the assignment, license, and transfer of patents, integrate minimum patent-use authorization standards, place on the defendant the onus in claims of product process infringement, and provide a protection term of at minimum twenty years from the filing date, or seventeen years from the grant date.[71] It is also important to note that domestic enforcement procedures relating to IP rights are available, and are required to be fair and equitable, not unnecessarily cumbersome, costly or complicated, with domestic adjudication based on the merits of the case in line with principles of due process and subject to appeal.[72]

---

[64] *Id.* NAFTA, Article 1703; Dorothy Schrader, Intellectual Property Provisions of the NAFTA, Congressional Research Service: Report to Congress 94-59A (21 January 1994), at 3-4.

[65] *Id.* Article 1709(1).

[66] *Id.* Article 1709(2-3).

[67] *Id.* Article 1709(4).

[68] *Id.* Article 1709(5-6).

[69] *Id.* Article 1709(7).

[70] *Id.* Article 1709(8).

[71] *Id.* Article 1709(9-12).

[72] *Id.* Article 1714(2-4), 1715(1).

IV. PATENT STANDARDS ACROSS NAFTA JURISDICTIONS

This section provides a discussion of the standards of patentability across NAFTA jurisdictions, with a focus on the promise utility doctrine and sound prediction. First, the theoretical background, legislative underpinning, and applicable jurisprudence relating to the promise utility doctrine in Canada is outlined. Second, patent standards in the United States are summarized, with an emphasis on highlighting the "enablement" and "written description" doctrines. Finally, patent standards applied in Mexico are briefly provided to illustrate similarities and differences across NAFTA. The promise utility doctrine, as developed in Canadian jurisprudence, is a unified articulation of core principles relating to patent scope, adequacy of disclosure, and timing of patent, which, while procedurally differentiated across NAFTA jurisdictions, goes to the heart of the patent bargain applied by all Parties when considered in relation to speculative patent practices.

A. Patent Law of Canada and the Patent Utility Doctrine

Patent protection, which in Canada is governed exclusively by the *Patents Act*,[73] is grounded in an essential bargain between the Crown and the inventor based on adequate public disclosure of a "novel," "unobvious," and "useful" invention in exchange for a term-limited monopoly intended to incentivize innovation.[74] Under the *Patents Act*, the invention in question must be a patentable subject-matter, be new, non-obvious, useful, and accompanied by sufficient disclosure in the patent itself.[75] Patentable subject matter relates to "all fields of technology," a notion encompassed in the Section 2 definition of "invention," which includes "any new and useful art, process, machine, manufacture or composition of matter," or an improvement to a previous patent,[76] including new uses of previously known compounds.[77] An invention is required to be new,[78] and not anticipated by a single reference of prior art.[79] Section 28.3 requires that the invention be non-obvious to a "person skilled in the art" on the date of claim.[80] Utility or "usefulness" which must be demonstrated or soundly predicted at the claim date,[81] is a further factor in the requirement for sufficient disclosure in the patent under Section 27(3), which

---

[73] Canada, Patents Act (1985), P-4.

[74] STEPHEN J. PERRY & T. ANDREW CURRIER, CANADIAN PATENT LAW (Markham, Ontario: LexisNexis, 2nd ed. 2014), at 39; ELIZABETH JUDGE & DANIEL GERVAIS, INTELLECTUAL PROPERTY: THE LAW IN CANADA (Toronto, Canada: Carswell, 2nd ed. 2011) at 643-646; AZT, *supra* note 28, ¶ 37; Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents), [1989] 1 S.C.R., 1623, 60 D.L.R. (4th)223, 25 C.P.R.(3d) 257, 97 N.R. 185 (S.C.C.) ¶ 25; Sanofi-Aventis v. Apotex Inc., [2009] F.C.J. No. 986 ¶ 358, 2009 FC 676 (F.C.), affd [2011] F.C.J. No 1532, 2011 FCA 300 (F.C.A.) leave to appeal refused [2012] S.C.C.A. No. 19 (S.C.C.).

[75] Canada Patents Act, *supra* note 73, § 2, 27(3), 27(8), 28.2(1), 28.3.

[76] *Id.* § 2, 32.

[77] Shell Oil Co. v. Canada (Patent Commissioner) [1982] 2 S.C.R. 536, ¶ 30-34.

[78] Canada Patents Act, *supra* note 73, § 2, 28.1, 28.2.

[79] *Id.* § 28.3.

[80] *Id.*

[81] AZT, *supra* note 28, ¶ 52.

requires that disclosure describe the invention in such detail and clear terms as to empower a person skilled in the art to bring about the desired effect.[82] It is the convergence of utility, sound prediction, and sufficient disclosure which brought to light the patent utility doctrine.

The exclusive rights encapsulated in a patent are not absolute, but are subject to satisfaction of the terms of the *Patents Act* and are reviewable and revocable through judicial interpretation at the Federal Court.[83] Patent utility has two core dimensions: first, the invention must provide something of commercial value, and second, the invention must be operable based on sufficient disclosure allowing a person skilled in the art to bring about the desired promise of the patent.[84] Where no specific promised result is made in the specification, a "mere scintilla" of utility is sufficient, but where a promised result is provided, utility must be considered by this measure.[85] The weighing of a patent's utility against a promise made in the specifications, a question of claim construction which substantively underpins the promise utility doctrine, is an inquiry wedded to the historical and theoretical justifications of the patent bargain.[86] Being imported from the English tradition, the promise utility doctrine has a longstanding judicial history in Canada,[87] with early authorities *New Process Screw, Consolboard and X. v. Canada (Patent Commissioner)* stressing a focus not on an assessment of the marketable value of the invention, but on the sufficiency of disclosure to bring about the promised outcome.[88] Early jurisprudence also illustrates the importance of a balanced scope to patent claims, with speculative or unachieved claims risking invalidation of the patent as a whole.[89] The principal question is whether a person skilled in the art, equipped with the disclosed specifications, can produce the invention.[90] More recent articulations in *Teva Canada Ltd. v. Pfizer Canada Inc.* and the aforementioned *Eli Lilly* and *Novopharm* saga reemphasized the well-established principle that patents, to have utility, must attain their implicit and explicit promises.[91]

---

[82] Canada Patents Act, *supra* note 73, § 27(3).

[83] *Id.* § 42, 60(1).

[84] Judge & Gervais, *supra* note 74, at 724; Eli Lilly & Co. v. Canada, Expert Report of Ronald E. Dimock (26 January 2015) ¶ 66-67.

[85] Laboratoires Servier v. Apotex Inc. [2008] F.C.J. No 1094, 2008 FC 825, ¶ 270; Consolboard, *supra* note 22.

[86] Perry & Currier, *supra* note 74, at 141; Eli Lilly, *supra* note 18, ¶ 80; Consolboard , *supra* note 22, ¶ 32; Tubes, Ld. v Perfecta Seamless Tube Company, Ld. (1902), 20 RPC 77.

[87] HALSBURY'S LAWS OF ENGLAND, vol. 29 (United Kingdom: Butterworth & Co, 3rd ed. 1960) at 59; Consolboard , *supra* note 22; Eli Lilly & Co. v. Canada, Government of Canada Counter Memorial ¶ 103 (2015); HAROLD G. FOX, CANADIAN PATENT LAW AND PRACTICE (Toronto: Carswell, 4th ed. 1969), at 153: "It is, therefore of the utmost importance to decide whether the specification makes a promise of a result and whether the ordinary workman would understand that that particular result is promised."

[88] Judge & Gervais, *supra* note 74, at 724-725; Consolboard , *supra* note 22, ¶ 36-37, 271-272; X. v. Canada (Patent Commissioner) (1981), 59 C.P.R. (2d) 7 46 N.R. 407, ¶ 4; New Process Screw Corp. v. PL Robertson Mfg Co. Ltd., (1961), 39 CPR 31 (Ex Ct), ¶ 33-34.

[89] Amfac Foods Inc. v. Irving Pulp & Paper, Ltd., (1986), 12 CPR (3d) 193 (FCA); Dimock Report, *supra* note 84, ¶ 75-81.

[90] Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents), [1989] 1 SCR 1623.

[91] Teva Canada Ltd. v. Pfizer Canada Inc., [2012] 3 SCR 625.

Utility must further be demonstrated or soundly predicted by the filing date.[92] The doctrine of sound prediction, which evolved in reply to patents for broad classes of compounds with only isolated testing, allows for patent utility to be asserted based on a factual basis and articulated line of reasoning which would empower a person skilled in the art to recognize the prediction as sound.[93] The three pillars of the doctrine of sound prediction were articulated in *AZT* to include: (i) a factual basis for the prediction, (ii) an "articulated" and "sound" line of reasoning as of the patent filing date, and (iii) proper disclosure.[94] Speculation, even if eventually fulfilled, is not sufficient to satisfy the patent bargain, as the public would be excluded from innovating while not gaining anything further than a hypothesis.[95] The doctrine of sound prediction is also highly dependent upon sufficient disclosure, with both the factual evidence and the line of reasoning supporting the prediction to be included.[96] Regarding the sufficiency of evidence to support the prediction, *Eurocopter*, relating to a mechanical invention, held that while testing of all variations is not needed, disclosure of some test data supporting the claimed configuration or composition is sufficient, bearing the evidence is not speculative but supports the production of the specific advantages.[97] Relating to the interface of pharmaceutical disclosure and sound prediction, *Pfizer Canada v. Mylan Pharmaceuticals ULC* citing *AZT* held that prior human trials relating to toxicity were not needed, noting the inquiry relates to utility not safety, and highlighting that sound prediction inherently indicates that "further work remains to be done."[98] Where a sound prediction in a selection patent is made, proposed advantages must be supported by sufficient evidence disclosed prior to the filing date,[99] with such evidence being tested in relation to the original group suggested to be sufficient.[100] Simply put, where a patent is based on a sound prediction, there is an increased emphasis on sufficient disclosure, and the prediction must be included in the description section of the patent,[101] so as to provide a solid teaching in exchange for the right to patent the invention.[102] The promise utility doctrine only applies where there is a "clear and unambiguous promise" in the patent.[103]

---

[92] AZT, *supra* note 28, ¶ 52, 56.

[93] Dimock Report, *supra* note 84, ¶ 98-100; Monsanto Company v. Commissioner of Patents, [1979] 2 SCR at 1108.

[94] AZT, *supra* note 28, ¶ 70; Judge & Gervais, *supra* note 74, at 728.

[95] *Id.* ¶ 84.

[96] Eli Lilly Canada Inc. v. Apotex Inc., [2008] F.C.J. No. 171, 2008 FC 142 (F.C.); Eli Lilly and Co v. Teva Canada Ltd, [2010] F.C.J. No 1115, ¶ 117.

[97] Eurocopter v. Bell Helicopter Textron Canada Ltée, [2012] F.C.J. No. 107, 2012 FC 113, ¶ 354, 368.

[98] Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC, [2012] F.C.J. No. 386, 2012 FCA 103, ¶ 53-54.

[99] Eli Lilly, *supra* note 20, ¶ 210.

[100] Apotex Inc. v. H. Lundbeck A/S, [2013] F.C.J. No. 274,2013 FC 192.

[101] Eli Lilly Canada Inc. v. Apotex Inc., [2009] F.C.J. No. 404, 2009 FCA 97, ¶ 14-15; Pfizer Canada Inc. v. Pharmsciences Inc., [2013] F.C.J. No.11, 2013 FC 120, ¶ 102-105.

[102] AZT, *supra* note 28, ¶ 69.

[103] Apotex Inc. v. Pfizer Canada Inc., [2014] FCA 250.

B. Patent Law of the United States and the Enablement and Written Description Doctrines

American patent law is governed through Chapter 35 of the United States Code.[104] A list of patentable subject matter – nearly identical to the s.2 definition of "invention" in Canada – is included in the §100 definition of "process," with patentable inventions identified in §101 as "any new and useful process, machine, manufacture or composition of matter. . . or improvement thereof."[105] Novelty, as set out in §102 must be satisfied, requiring the patented subject matter not to be previously patented, described in a publication, or publicly available, with a one-year grace period provided negating prior disclosure made by the inventor equating to prior art or anticipation.[106] Recent reforms have also implemented a "first to file" model bringing the U.S. practice in-line with international practice.[107] As per §103 the patented invention must also be non-obvious to a person skilled in the art.[108] While the notion of utility is encapsulated in "useful" under §101, American jurisprudence has elaborated three distinct criteria: (i) the invention must provide credible utility to a person skilled in the art (operability),[109] (ii) the utility in question must be specific in nature (specific) and (iii) provide a substantial or practical benefit.[110]

This bifurcated approach assesses not just utility, in as much as the invention must have a specific use, but also operability, in as much as the invention must be capable of achieving the benefit of the patent.[111] A patent must include an "assertion of utility,"[112] a notion comparable to a promise in Canadian jurisprudence, well-described in non-generic and specific language,[113] which at the time of filing is grounded in sufficient data supporting the desired results of the invention.[114] As set out in §112(a), patent specification shall contain "a written description of the invention," which must clearly enable a person skilled in the art to "make and use" the claimed invention, including guidance on the

---

[104] United States, Chapter 35, United States Code (as amended 2012) [35 U.S.C.].

[105] *Id.* §100-101.

[106] *Id.* §102(a-b).

[107] United States, Act To Correct and Improve Certain Provisions of the Leahy-Smith America Invents Act and Title 35, United States Code, HR 6621 (Public Law No.112-274, 126 Stat. 2456).

[108] 35 U.S.C., *supra* note 104, §103.

[109] Process Control Corp. v. HydReclaim Corp., United States Court of Appeals, Federal Circuit, 190 F.3d 1350, 1358, 52 USPQ2d 1029, at 1034 (Fed. Cir. 1999); In re Mitchell R. Swartz, United States Court of Appeals, Federal Circuit, 232 F.3d 862 (Fed. Cir. 2000), at 1-2.

[110] In re Fisher, United States Court of Appeals, Federal Circuit, 421 F.3d 1365 (Fed. Cir. 2005), at 9-10; Eli Lilly & Co. v. Canada, Expert Report of Timothy R. Holbrook (26 January 2015), ¶ 20.

[111] E. Richard Gold & Michael Shortt, The Promise of the Patent in Canada and Around the World, 30:1
Canadian Intellectual Property Review 35, (2014), at 32-33.

[112] In re Bremner, 182 F.2d 216 at 216(CCPA 1950); In re Fisher, *supra* note 110, at 10-11.

[113] In re Kirk, 376 F.2d 936, (C.C.P.A. 1967), at 941.

[114] Cre-Agri, Inc. v. Pinnaclife, Inc., No.: 11-CV-6635-LHK, 2013 WL 6673676, at 16 (N.D. Cal. Dec. 18, 2013); Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1325 (Fed. Cir.2005).

best mode contemplated for the invention, and shall include one or more specific claims distinctly illustrating the subject-matter of the invention.[115] The enablement doctrine articulated in the §112 requirement of "written description" is equitable to sufficient description obligations in Canada,[116] and serves a dual purpose, of "ensuring adequate disclosure" and dissuading overly broad claims or "invention without experimentation."[117] While the promise utility doctrine remains a construct of the Anglo-Canadian tradition, significant substantive alignment can be found in the American approaches relating to the "written disclosure," "operability," "enablement," and "assertion of utility" doctrines.[118]

C. Patent Law of Mexico

Mexico, whose domestic IP system underwent significant reform in 2010,[119] approaches utility through the doctrine of "industrial application."[120] An invention, characterized as any human creation which transforms energy or matter to address a concrete need,[121] is required to be new, involve an "inventive activity" and be capable of industrial application.[122] Novelty and non-obviousness are assessed in relation to the state of the art on the filing date, with a one-year grace period provided for patenting.[123] As per Article 12, the patent must include a written description of: (i) everything new which is contributed to the state of the art, (ii) the current state of the art, (iii) the creative process which is non-obvious to a person skilled in the art, (iv) the practical utility or use in commerce, and (v) the claimed essential characteristics.[124] Article 47 stresses that the description needs sufficient clarity and comprehensiveness to enable a full understanding and actualization of the invention by a person skilled in the art, including best-known methods of execution, and underlying information establishing the industrial applicability.[125] Additional information may also be requested or required by patent authority to support any information provided in the patent application during the processing.[126] Insufficient disclosure or "descriptive insufficiency" is seen as synonymous with "lack industrial applicability," but admittedly these concepts are underdeveloped.[127]

---

[115] 35 U.S.C., *supra* note 104, at §112(a-b); Cre-Agri, *supra* note 114; Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010).

[116] Gold & Shortt, *supra* note 111, at 35.

[117] *Id.*; MagSil Corp. v. Hitachi Global Storage Techs., Inc., 687 F.3d 1377, No. 2011–1221 (2012; Holbrook Report, *supra* note 110, at 17.

[118] Gold & Shortt, *supra* note 111, at 38-40; Holbrook Report, *supra* note 110, ¶ 6.

[119] Eli Lilly & Co. v. Canada, Expert Report of Hedwig Lindner (26 January 2015), ¶ 27.

[120] Industrial Property Act, Official Diary of the Federation of June 27, 1991, (Last Reform, Official Diary of the Federation of April 9, 2012), at Article 16; unofficial translation of Ley de la Propiedad Industrial, Diario Oficial de la Federación el 27 de junio de 1991, (Última reforma publicada DOF 09-04-2012) [Industrial Property Act].

[121] *Id.* Article 15.

[122] *Id.* Article 16.

[123] *Id.* Article 17-18.

[124] *Id.* Article 12.

[125] *Id.* Article 47.

[126] *Id.* Article 55.

[127] Lindner Report, *supra* note 119, ¶ 82.

V. COMPATIBILITY OF THE PROMISE UTILITY DOCTRINE AND OBLIGATIONS UNDER NAFTA

This section will evaluate the consistency of the promise utility doctrine with NAFTA obligations as seen in the cases of Zyprexa (olanzapine) and Strattera (atomoxetine). Three key questions will be discussed: (i) if the promise utility doctrine denies treatment guaranteed under the minimum standard of treatment; (ii) if the application of the promise utility doctrine results in direct or indirect expropriation; (iii) if the promise utility doctrine is incompatible with the established IP norms. First, the reasonably expected standard of treatment under Article 1102, 1103, 1105, and 1703 is considered. Second, an inquiry of expropriation under Article 1110 is provided. Lastly, the promise utility doctrine is reviewed in relation to international IP norms and subsequent alignment with Article 1709. The promise utility doctrine is an evolutionary articulation of longstanding NAFTA compliant IP principles driven by an enhanced need for enforcement of adequate disclosure standards to maintain the patent bargain in a new and rapidly developing age of innovation.

A. An Inquiry into the Standard of Treatment

In evaluating the standard of treatment under Article 1105, core principles of consideration are FET and "legitimate expectations."[128] Regarding the former, in *Waste Management II* it was noted that Article 1105 does not create an open-ended review mechanism;[129] rather the focus remains on egregious conduct or lack of due process, with the tribunal suggesting the FET principle is violated in cases of state conduct which is "arbitrary, grossly unfair . . . [or] lack[s] due process."[130] Where there is a denial of justice, a systemic analysis is often conducted,[131] as illustrated in *Metalclad* (refusal by a municipal authority to issue construction permit), *Tecmed* (revocation of a license to operate), *Loewen* (propriety of court proceedings), and *Petrobart* (state intervention in the execution of a judgment).[132] As noted in *BilCon*, the categorical formula put forward in *Waste Management* while "particularly apt" also conveys a high threshold of conduct to equate to a breach of Article 1105.[133] The national treatment and most favorable nation standards grounded in Article 1102 and

---

[128] Bonnitcha, *supra* note 55, at 147, 152-153.

[129] Waste Management Inc. v. United Mexican States ("Number 2"), Award, ICSID ARB(AF)/00/3, ¶ 94-98 (2004); S.D. Myers, Inc. v. Government of Canada, (UNCITRAL), Partial Award ¶ 261, 263 (2000).

[130] Waste Management II, *supra* note 129, ¶ 94-98; The Loewen Group, Inc. and Raymond L. Loewen v. United States of America, Award (Case No. ARB (AF)/98/3) ¶ 124-126 (2003).

[131] Waste Management II, *supra* note 129, ¶ 97.

[132] Dolzer & Schreuer, *supra* note 35, at 142-144; Metalclad, *supra* note 59; Tecmed v Mexico, No. ARB (AF)/002, at 133 (2003); Loewen, *supra* note 130; Petrobart v Kyrgyz Republic, Award, SCC Case No. 126/2003 (2005).

[133] William Ralph Clayton, William Richard Clayton, Douglas Clayton, Daniel Clayton and Bilcon of Delaware Inc v. Government of Canada, Award on Jurisdiction and Liability, PCA 2009-04 ¶ 443-444 (2015).

1103 respectively, also incorporate factors such as "like circumstances," and if the measure places a foreign investment at a "disproportionate disadvantage."[134]

The judicial invalidations of patent 113 relating to Zyprexa (olanzapine) and patent 735 relating to Strattera (atomoxetine) were made in accordance with the standards of FET and national treatment. While Eli Lilly claim the 113 and 735 patent decisions specifically, and the underlying jurisprudence supporting the promise utility doctrine more broadly, are "improper and discreditable,"[135] I find this position difficult to support. In both cases, Eli Lilly received fair and impartial protection and treatment under the law, with transparent and substantively sound forums for due process. As noted in *Mondev*, when considering judicial decisions, the test is not if the result was "surprising," but if the result calls into question the "juridical propriety" of the decision, with international tribunals explicitly recognized as "not courts of appeal."[136] An Article 1105 inquiry is concerned with identification of a denial of justice, discrimination,[137] or arbitrariness in the judicial process,[138] rather than providing a substantive review of valid decisions made by domestic authorities.[139] The invalidation of the 113 and 735 patents were grounded in longstanding legal principles established far prior to the establishment of NAFTA.[140] If, as noted in *Bilcon*, the investor can expect, absent any changes in domestic law, to have a case assessed on the "merits," based on the "same legal standards applied to applicant[s] generally," then indeed Eli Lilly did receive their legitimate expectations of a sound legal framework and developed patent law, contrary to their assertion.[141] The 113 and 735 patents simply failed on their merits, which is not a valid violation of the principle of FET. Deference must always be paid to domestic courts in the determination of property and application of interpretive techniques unless such action calls into question the judicial propriety of the system.

B. An Inquiry into the Expropriation

When considering under Article 1110 if a measure is, or is tantamount to, expropriation directly or indirectly, tribunals have taken differing approaches: (i) looking "exclusively" at the effects of the measure to the investment in question (*Metalclad, Pope & Talbot*), (ii) looking at the effects more broadly, subject to outlined exceptions (*Methanex*), and (iii) a balancing approach which considers both the effects and the characteristics of the measure (*Feldman*).[142] Conceptually, direct and indirect expropriation are often differentiated on the

---

[134] Pope & Talbot, *supra* note 47, ¶ 43.
[135] Canada, Notice of Arbitration, *supra* note 2, ¶ 81.
[136] Mondev International Ltd. v. United States of America, Award, ICSID Case No. ARB (AF)/99/2, ¶ 127 (2012).
[137] Waste Management II, *supra* note 129, ¶ 129-130; Loewen, *supra* note 130.
[138] ELSI, *supra* note 46, ¶ 128.
[139] Mondev, *supra* note 136, ¶ 133.
[140] Consolboard, *supra* note 22.
[141] Notice of Arbitration, *supra* note 2, ¶ 82.
[142] Bonnitcha, *supra* note 55, at 230.

grounds of the impact of the measure on the legal title of the investment,[143] with the phrases "tantamount to expropriation" interpreted as equating to indirect expropriation.[144] An "investment" for the purposes of Article 1110(1) includes legitimately acquired property interests – both tangible and intangible.[145]

Two distinct lines of inquiry relating to the influence of the "effects" of indirect expropriation exist, exemplified by *Metalclad* and *Pope & Talbot* respectively.[146] In *Metalclad*, where denial of a municipal construction permit and passing by the state of an "Ecological Decree" inhibited operation of a proposed hazardous waste landfill, the tribunal defined expropriation to include "covert or incidental interference" with a property interest which deprives the investor "in whole or significant part" of the "reasonably-to-be-expected economic benefit" of the property.[147] Subsequent decisions in *Occidental v. Ecuador (II),* and *Chemtura v. Canada* have somewhat distanced themselves from the "broad definition" applied in *Metalclad*, adopting without application the standard.[148] An alternative approach was applied in *Pope & Talbot*, where an export quota on softwood lumber was set in place, with the tribunal classifying the ability to export the product as an independent property interest from the business as a whole,[149] with expropriation of that property interest required to be a "substantial deprivation."[150] The standard of "substantial deprivation" has been endorsed in *Fireman's Fund* and *Chemtura*,[151] albeit prior to a balancing exercise.[152] Subsequent applications of the *Pope & Talbot* standard have highlighted various practices which amount to indirect expropriation, including notably, deprivation of control over the investment, or deprivation of property in whole or in part,[153] and noted the need for the substantial interference to actually cause economic harm[154] and involve deprivation of all or a significant part of the property interest.[155]

An exception to the general rule against expropriation was established in *Methanex*, where an environmentally focused regulatory scheme was upheld on the grounds that a "non-discriminatory regulation for a public purpose," implemented in accordance with principles of due process and previous

---

143 Dolzer & Schreuer, *supra* note 35, at 92.

144 Pope & Talbot v. Canada, Interim Award, 26 June 2000, ¶ 96; Feldman v. Mexico, Award, ICSID Case No. ARB(AF)/99/1, ¶ 100 (2002); SD Myers v. Canada, *supra* note 129, ¶ 286; Waste Management II, *supra* note 129, ¶ 155.

145 NAFTA, *supra* note 1, Article 1139.

146 Bonnitcha, *supra* note 55, at 247; Chemtura v. Canada, (2 August 2010) ¶ 249.

147 *Metalclad*, *supra* note 59, ¶ 103.

148 Chemtura, *supra* note 146, ¶ 248; Occidental v. Ecuador (I), Final Award, UN No. 3467 ¶ 87-88 (2004).

149 Pope & Talbot Interim Award, *supra* note 144, ¶ 4, 98.

150 *Id.* ¶ 102.

151 Chemtura, *supra* note 146 at para 249; *Fireman's Fund v. Mexico,* Award, 17 July 2006, ICSID Case No. ARB (AF)/02/1, ¶ 176.

152 Bonnitcha, *supra* note 55, at 251-252.

153 Sempra Energy, *supra* note 60, ¶ 284.

154 Bayindir v. Pakistan, Award, ICSID Case No. ARB/03/29, ¶ 458-460 (2009).

155 Grand River Enterprises Six Nations Ltd. et al. v. United States, Award, ¶ 151 (2011); Bosh v. Ukraine, Award, ICSID Case No. ARB/08/11, ¶ 210 (2012).

international commitments, was not deemed expropriation.[156] Similarly, in *Saluka* enforcement of banking regulations resulting in liquidation of the investment was upheld as a valid exercise of regulatory authority "aimed at the general welfare."[157] Subsequent tribunals have applied the requirements of public policy and due process from *Methanex* to cases involving cancelation of a tariff index framework, and cancelation of an operation permit, under the "police powers" exception for valid exercises of domestic authority.[158] A further approach was adopted by the tribunal in *Tecmed*, where cancelation of a license to operate after a year of operation was deemed to be indirect expropriation on the grounds of reasonable expectations, and rejecting a broad exception, alternatively indicated the need for proportionality between the measure and the aim sought.[159] Likewise, in *Azurix* and *LG&E* the tribunal reiterated the general welfare exception requiring the measure not be "obliviously disproportionate to the need being addressed."[160] Finally, in *Feldman* v. *Mexico* the principal question pertained to if the measure was a valid governmental activity; the tribunal taking a holistic view of the circumstance, balanced the character and effects of the measure and considered: (i) the general nature of the measure, (ii) the rational public purpose, (iii) the deprivation of rights, and (iv) retention of control of the investment.[161]

The judicial invalidations of patent 113 and patent 735 were not expropriation of a valid property interest under Article 1110(1). First, the invalidation of the aforementioned patents through application of the promise utility doctrine extinguished the validity of the property interest for the purposes of Article 1139 and 1110(1), as only domestic law may determine the validity of a property interest.[162] Second, application of the promise utility doctrine did not amount to a substantial deprivation under *Pope & Talbot.* While the judicial proceedings resulted in the patents being invalidated, Eli Lilly had enjoyed their exclusive rights for nearly the full term, still retained the ability to sell the products, albeit at a reduced margin of sale, and still retained a highly successful enterprise with a wide spectrum of financial and property interests. The aforementioned patents were only two in a stable of IP interests by Eli Lilly, the depth, breadth, or value of which was not substantially diminished. Looking at substantial deprivation holistically as was done in *Feldman*, the enforcement of patent rights serves as a valid public purpose, with invalidation being the sole proportionate outcome. Maintenance of the patent bargain by way of requiring

---

[156] Methanex, *supra* note 61, ¶ 7–15.

[157] Saluka, *supra* note 61, ¶ 255.

[158] AWG Group v. Argentina, Decision on Liability, ICSID No. ARB/03/19, ¶ 140 (2010); Chemtura, *supra* note 146, ¶ 266; Bonnitcha, *supra* note 55, at 257-259.

[159] Tecmed, *supra* note 132, ¶ 116, 119-122.

[160] Azurix v. Argentina, Award, ICSID Case No.ARB/01/12, ¶ 316 (2006); LG&E Energy v. Argentina, Decision on Liability, ICSID Case No. ARB/02/01, ¶ 195, 200 (2006).

[161] Feldman, *supra* note 144, ¶ 111-116, 136-137.

[162] Emmis International Holding, B.V. Emmis Radio Operationg, B.V. Mem Magyar Electronic Media Kereskedelmi Es Szolgaltato KT v. Hungary, Award, ICSID Case No. ARB/12/2, ¶ 161-162 (2014); EnCana Corporation v. Republic of Ecuador, (UNCITRAL) Award, LCIA Case No. UN3481, ¶ 184 (2006).

the patent to achieve the claimed end, ensures the public is provided with adequate instructions to achieve the benefit of the invention in return for the term limited monopoly, and is vital to guaranteeing that innovation remains enabled to develop and build upon the prior art. Finally, if presumptively expropriation *prima facie* could be found, the actions relating to the 113 and 735 patents are valid exceptions under the *Methanex*, *Saluka*, *Azurix* and *LG&E* "police powers doctrine." The promise utility doctrine is a non-discriminatory application of legislation, in accordance with due process and prior international commitments, and in support of an integral public purpose – upholding the patent bargain.

C. An Inquiry into Intellectual Property

When assessing the exemption of measures relating to the issuance or revocation of IP rights under Article 1110(7), alignment of the measure with obligations under Article 1709(1) and 1709(7-8) is a principal area of focus. First, Article 1709(1) contains substantively equivalent language to TRIPS Article 27(1),[163] requiring patents be allowed in "all fields of technology" bearing they are "new," involve an "inventive step," and are "capable of industrial application," with "inventive step" and "capable of industrial application" synonymous with "non-obvious" and "useful." These notions are each integrated into the domestic legislation of NAFTA Parties through the definitions of "invention" in Canada,[164] "process" in the United States,[165] and "industrial application" in Mexico.[166] Additionally, the explicit reference that "inventive step" and "capable of industrial application" are equivalent to "non-obvious" and "useful,"[167] implicitly imports a recognition of the parallel legal traditions and subsequent differential jurisprudence.

Second, Article 1709(7) prohibits patent discrimination on the grounds of the type of technology, or place of production. While it is claimed that pharmaceutical patents are disproportionately targeted,[168] as a component of the Common Law, in actuality the promise utility doctrine is applied across all patents regardless of technology, and has been utilized in consideration of both mechanical and chemical patents.[169] Any disproportionality in form or effect is a result of the endemic nature of speculative and overly broad patent practices in the pharmaceutical industry generally.[170] Third, Article 1709(8) provides that a patent may be revoked where grounds exist which would have justified refusal for the patent to be granted. Illustrating the alignment of the promise utility

---

[163] Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, UNTS Volume 1867, No 31874, Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 27(1).

[164] Canada Patents Act, *supra* note 73, s. 2, 28.

[165] 35 U.S.C., *supra* note 104, §100-101.

[166] Mexico Industrial Property Act, *supra* note 120, Article 16.

[167] NAFTA, *supra* note 1, at Article 1709(1).

[168] Canada, Claimants Memorial, *supra* note 6, ¶ 186.

[169] Eurocopter, *supra* note 97; New Process Screw, *supra* note 88; Dow Chemical Company v. NOVA Chemicals Corporation, [2014] FC 844.

[170] Ikechi Mgbeoji and Byron Allen, *Patent First, Litigate Later! The Scramble for Speculative and Overly Broad Genetic Patents: Implications for Access to Health Care and Biomedical Research*, 2 CANADIAN JOURNAL OF LAW AND TECHNOLOGY 2, 83-98 (2003).

doctrine, the utility of an invention as noted in *AZT* must be demonstrated or soundly predicted by the filing date, based on a sound line of reasoning, or the patent would be "offering nothing to the public but wishful thinking."[171]

Fourth, some divergence in the legislative implementation of international IP standards is tolerated under international law,[172] with the independence of patent jurisdictions reinforced in Article *4bis* of the Paris Convention.[173] As seen in *Harvard Mouse*, where a method patent was allowed but the patent on the higher life form rejected on the interpretation of "invention" in contrast to other jurisdictions, while global trade makes it desirable for differing IP jurisdictions to come to "similar legal results," it is important to allow for statutory interpretation based on the purpose of the Act contextualized by key public policy concerns, which at times brings about divergent results.[174] The utility standard as applied in Canada, under the promise utility doctrine, and in the United States, under the doctrines of "enablement" and "written description," achieve technically and substantively similar results through enforcing differing aspects of the patent bargain.[175]

Fifth, while substantively similar, the divergence between the Canadian and U.S. approaches to utility is procedural in nature.[176] Under the U.S. system, once the patent holder proves an infringement has occurred, the infringing party is estopped from questioning the utility of the invention, leaving utility and patent bargain inquiries practically occurring under the doctrines of "written disclosure," "operability," "enablement," and "assertion of utility."[177]

Sixth, the uniform substantive principles applied across NAFTA jurisdictions aim to address an important public policy concern – the prevention of speculative patents – with each jurisdiction's judiciary placing emphasis on differing operative elements of the domestic patent framework. On utility the NAFTA jurisdictions have developed a common-but-differentiated approach on utility where Canada utilizes the promise utility doctrine coupled with sound prediction,[178] the United States cites operability, enablement and written description doctrines,[179] and Mexico views "descriptive insufficiency" as

---

[171] AZT, *supra* note 28, ¶ 52, 56.

[172] D. HALJAN, SEPARATING POWERS: INTERNATIONAL LAW BEFORE NATIONAL COURTS, at 31-61, 73-79 (Netherlands: Springer, 2013); Eli Lilly & Co. v. Canada, Second Expert Report of Dr. Daniel Gervais, ¶ 11-12 (7 December 2015).

[173] Paris Convention on the Protection of Industrial Property, (signed 20 March 1883, as amended 1979), at Article 4*bis*.

[174] Harvard Collage v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, ¶ 153-155, 176-177.

[175] Gervais Report, *supra* note 170, ¶ 17; Dimock Report, *supra* note 84, ¶ 12, 114.

[176] Gold & Shortt, *supra* note 111, at 33-34.

[177] *Id.* at 34; EI du Pont de Nemours & Co v Berkley & Co Inc., 620 F.2d 1247, 1260 n 17, at 128 (8th Cir 1980).

[178] Consolboard, *supra* note 22; Pfizer, *supra* note 91; *Eli Lilly* 2011 FC 1288, *supra* note 20; AZT, *supra* note 28.

[179] 35 U.S.C., *supra* note 104, at §112(a-b); Cre-Agri, *supra* note 114; Ariad Pharm., *supra* note 115.

synonymous with "lack [of] industrial applicability,"[180] each achieving the same technical result of ensuring fulfillment of the promise of the patent.

Lastly, a critical consideration in the overall analysis hinges on the suggestion that in upholding one norm (the promise utility doctrine), the SCC has invariably breached another set of international legal norms – namely, FET. However, such a pre-emptive conclusion assumes both that international legal norms are fixed with objectively identifiable components, and that any perceived interpretive deviation by domestic courts is a 'violation' rather than an articulation of an emerging normative standard underlying *opino juris.*[181] For instance, the definition of "ship" applied domestically by the Greek judiciary under the global regime on civil liabilities for oil pollution damage, has influenced the approach adopted by Parties under the International Maritime Organization ("IMO") regime.[182] Similarly, UK jurisprudence has at times been influential in the interpretation and application of law under the European Court of Human Rights.[183] The approach adopted in Canadian jurisprudence grows from a unique mix of market circumstances which nurtured the promise utility doctrine, namely a market saturated by highly aggressive foreign competitors who, through use of overly aggressive patenting practices, have allowed vulnerabilities which invariably are exploited by domestic competitors. Articulation of the promise utility doctrine is responsive to speculative patent practices of market actors, and upholds the theoretical underpinnings of the patent system.

VI. CONCLUDING THOUGHTS

The promise utility doctrine, as seen applied in the cases of Zyprexa and Strattera, illustrates application of longstanding legal principles to uphold the public purpose of the patent bargain, and dissuade overly broad patent practices. Indeed, the invalidations of the 113 and 735 patents initially seemed counterintuitive, but were legally sound when considered juxtaposed to a doctrinal evaluation of the patents' promise and relative disclosure. Practically, the 113 and 735 patents failed for lack of utility, not by virtue of a lack of commercial application, but by virtue of the fact that the patent did not functionally provide for the thing that was patented. The patent is an accord with an inventor allowing a short term monopoly over a specific new or novel process or thing, in exchange for accurate disclosure – in particular, based on verifiable,

---

[180] Industrial Property Act, *supra* note 120, Article 12, 16, 47.

[181] ANTONIOS TZANAKOPOULOS, PRINCIPLES ON THE ENGAGEMENT OF DOMESTIC COURTS WITH INTERNATIONAL LAW, PRELIMINARY REPORT, INTERNATIONAL LAW ASSOCIATION STUDY GROUP: PRINCIPLES ON THE ENGAGEMENT OF DOMESTIC COURTS WITH INTERNATIONAL LAW ¶ 5, 30 (2012).

[182] *Id.* ¶ 31; International Convention on Civil Liabilities for Oil Pollution Damage (1992), IMO; International Oil Pollution Compensation Fund (1992) IMO; International Oil Pollution Compensation Fund, Liability and Compensation for Oil Pollution Damage: Texts of the 1992 Civil Liability Convention, the 1992 Fund Convention and the Supplementary Protocol (London: IOPCF, 2011).

[183] Tzanakopoulous, *supra* note 181, ¶ 31.

quantifiable, and enduring findings supporting a sound prediction – allowing another skilled in the art to build upon that knowledge once in the public domain. If a patent is allowed to make multiple expansive promised applications, then indeed it should be measured against the actualization of those proposals or risk, broadly inhibiting innovation and market competition in general. This was never the intention of the patent and is a distortion of the system.

While procedural divergence may be identified across NAFTA jurisdictions relating to a utility, theoretically and substantively, the Parties apply arguably equitable technical inquiries. The invalidations of the 113 and 735 patents were in line with IP obligations under Chapter 17 of NAFTA, and as such, are exempted from consideration as expropriation under Article 1110(7). Furthermore, the invalidations in-and-of-themselves extinguished the valid property interests underlying an expropriation inquiry, with the judicial application of the promise utility doctrine through a practice of due process, upheld as a valid and proportionate exercise of domestic authority, should such an inquiry occur. It would be a distortion and contrary to the object and purpose of the treaty to suggest that the standard established under Article 1709 accommodates overly broad or unsubstantiated patent practices.

The promise utility doctrine demonstrates a natural and logical articulation of patent law which is consistent with the substantive and procedural requirements of NAFTA. The elements which make up the promise utility doctrine are derived from the longstanding synergies of inventiveness and adequate disclosure in relation to the patent bargain, and are grounded in the principle of FET treatment. In essence, the promise utility doctrine enforces the material point of the patent system: a specific and adequately disclosed invention which manifestly achieves the inventive promise of the patent. Overly broad or speculative patent practices have chilling effect on innovation through the creation of bottle-necks or inadvertent research monopolies. In an age of rapid technological innovation, the promise utility doctrine acts to soften the suppressive effects of speculative patent practices on innovation and trade in a manner consistent with NAFTA.