

**IN THE MATTER OF THE ARBITRATION UNDER CHAPTER ELEVEN OF THE
NORTH AMERICAN FREE TRADE AGREEMENT AND THE UNCITRAL
ARBITRATION RULES**

BETWEEN:

ELI LILLY AND COMPANY,

Claimant

AND

GOVERNMENT OF CANADA,

Respondent

CASE NUMBER UNCT/14/2

AMICUS BRIEF OF THE NATIONAL ASSOCIATION OF MANUFACTURERS

February 12, 2016

Linda E. Kelly
Patrick N. Forrest
Leland P. Frost
NATIONAL ASSOCIATION OF
MANUFACTURERS
733 10th Street NW, Suite 700
Washington, DC 20001
202.637.3000

Charles Owen Verrill, Jr.
Maureen E. Thorson
Brian H. Pandya
WILEY REIN LLP
1776 K Street NW
Washington, DC 20006
202.719.7000

TABLE OF CONTENTS

	Page(s)
I. INTRODUCTION AND OVERVIEW	1
II. CANADA’S PROMISE UTILITY DOCTRINE DEPARTS FROM ESTABLISHED INTERNATIONAL NORMS	4
A. Overview of How Manufacturers Globally Protect Their Innovations	4
B. NAFTA Guarantees Baseline Protections for Patents	7
C. Canada’s Promise Utility Doctrine Creates an Unpredictable and Unstable Regulatory Regime	9
III. JUDICIAL DECISIONS MAY RESULT IN EXPROPRIATION COGNIZABLE UNDER NAFTA ARTICLE 1110.....	11
IV. NAFTA ARTICLE 1105(1) REQUIRES FET AS REFLECTED IN CURRENT CUSTOMARY INTERNATIONAL LAW	12
A. The Status and Operation of FET in International Investment Treaties	12
B. NAFTA Article 1105(1) Requires FET as a Minimum Standard of Treatment of Alien Investments and Investors	13
C. Customary International Law Standards Have Evolved.....	14
V. CONCLUSION.....	20

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>In re Anthony</i> , 414 F.2d 1383 (C.C.P.A. 1969)	10
Available at https://casetext.com/case/application-of-anthony	
<i>Azinian et ors. v. Mexico</i> , ICSID Case. No. ARB(AF)/97/2, Award (Nov. 1, 1999).....	11
Available at http://www.italaw.com/sites/default/files/case-documents/ita0057.pdf .	
<i>Cargill, Inc. v. Mexico</i> , ICSID Case No. ARB(AF)/05/2, Award (Sept. 18, 2009)	19
Available at http://www.italaw.com/sites/default/files/case-documents/ita0133_0.pdf .	
<i>Case Concerning Elettronica Sicula S.p.A. (ELSI)</i> , 1989 I.J.C. 15 (July 20).....	16
Available at http://www.icj-cij.org/docket/files/76/6707.pdf .	
<i>Chemtura Corp. v. Canada</i> , UNCITRAL/NAFTA, Award (Aug. 2, 2010).....	17, 18
Available at http://www.italaw.com/sites/default/files/case-documents/ita0149_0.pdf .	
<i>Glamis Gold, Ltd. v. U.S.A.</i> , UNCITRAL/NAFTA, Award (June 8, 2009).....	18
Available at http://www.italaw.com/sites/default/files/case-documents/ita0378.pdf .	
<i>Int’l Thunderbird Gaming Corp. v. Mexico</i> , UNCITRAL/NAFTA, Award (Jan. 26, 2006).....	17
Available at http://www.italaw.com/sites/default/files/case-documents/ita0431.pdf .	
<i>In re Krimmel</i> , 292 F.2d 948 (C.C.P.A. 1961)	8
<i>L.F.H. Neer & Pauline Neer (U.S.A.) v. Mexico</i> , 4 R.I.A.A. 60 (U.S.-Mex. Gen. Claims Comm’n Oct. 15, 1926).....	15, 18
Available at http://legal.un.org/riaa/cases/vol_IV/60-66.pdf	
<i>Lowell v. Lewis</i> , 15. F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568)	10
Available at https://law.resource.org/pub/us/case/reporter/F.Cas/0015.f.cas/0015.f.cas.1018.2.pdf	
<i>Merrill & Ring Forrestry L.P. v. Canada</i> , UNCITRAL/NAFTA, Award (Mar. 31, 2010)	19, 20

Available at <http://www.italaw.com/sites/default/files/case-documents/ita0504.pdf>.

Metalclad Corp. v. Mexico, ICSID Case No. ARB(AF)/97/1, Award (Aug. 30, 2000).....14

Available at <http://www.italaw.com/sites/default/files/case-documents/ita0504.pdf>.

Mondev International Ltd. v. U.S.A., ICSID Case No. ARB(AF)/99/2, Award
(Oct. 11, 2002)16, 17

Available at <http://www.italaw.com/sites/default/files/case-documents/ita1076.pdf>.

Pope & Talbot Inc. v. Canada, UNCITRAL/NAFTA, Award in Respect of Damages
(May 31, 2002).....15, 16

Available at <http://www.italaw.com/sites/default/files/case-documents/ita0686.pdf>.

Pope & Talbot Inc. v. Canada, UNCITRAL/NAFTA, Interim Award (June 26, 2000)14

Available at <http://www.italaw.com/sites/default/files/case-documents/ita0674.pdf>.

Railroad Development Corp. v. Guatemala, ICSID Case No. ARB/07/23, Award
(June 29, 2012).....15

Available at <http://www.italaw.com/sites/default/files/case-documents/ita1051.pdf>.

S.D. Myers Inc. v. Canada, UNCITRAL/NAFTA, Partial Award (Nov. 13, 2000).....14

Available at <http://www.italaw.com/sites/default/files/case-documents/ita0747.pdf>.

Vornado Air Circulation Sys. v. Duracraft Corp., 58 F.3d 1498 (10th Cir. 1995)8

Available at <http://caselaw.findlaw.com/us-10th-circuit/1198562.html>

Waste Management, Inc. v. Mexico, ICSID Case No. ARB(AF)/00/3, Award
(Apr. 30, 2004).....19

Available at <http://www.italaw.com/sites/default/files/case-documents/ita0900.pdf>.

Treaties

North American Free Trade Agreement, art. 1105.1, Dec. 17, 1992, 32 I.L.M. 605 (1993).....13

Available at <http://www.sice.oas.org/trade/nafta/chap-111.asp#A1105>.

North American Free Trade Agreement, art. 1701.1, Dec. 17, 1992, 32 I.L.M. 605 (1993).....7

Available at <http://www.sice.oas.org/trade/nafta/chap-171.asp#A1701>.

North American Free Trade Agreement, art. 1702, Dec. 17, 1992, 32 I.L.M. 605 (1993).....	8
<i>Available at http://www.sice.oas.org/trade/nafta/chap-171.asp#A1702.</i>	
North American Free Trade Agreement, art.1709.1, Dec. 17, 1992, 32 I.L.M. 605 (1993).....	8
<i>Available at http://www.sice.oas.org/trade/nafta/chap-171.asp#A1709.</i>	
Patent Cooperation Treaty, art. 33, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.....	6
<i>Available at http://www.wipo.int/pct/en/texts/articles/a33.htm.</i>	

Other Authorities

Am. Law Inst., RESTATEMENT OF THE LAW (3D), FOREIGN REL. LAW OF THE UNITED STATES (2015).....	14
Christian Tietje & Freya Baetens, <i>The Impact of Investor-State Dispute Settlement (ISDS) in the Transatlantic Trade and Investment Partnership</i> (June 24, 2015).....	13
<i>Available at http://media.leidenuniv.nl/legacy/the-impact-of-investor-state-dispute-settlement-isds-in-the-ttip.pdf.</i>	
Derrick T. Jennings and James J. Fetzer, <i>Direct Investment Positions for 2014: Country and Industry Detail</i> , 95 SURV. CURRENT BUS. 7, July 2015.....	1
<i>Available at http://www.bea.gov/scb/pdf/2015/07%20July/0715_direct_investment_positions.pdf.</i>	
Donald S. Chisum, 1 CHISUM ON PATENTS (2015).....	8, 10
Edmund W. Kitch, <i>The Nature and Function of the Patent System</i> , 20 J.L. & ECON. 265 (1977).....	5
EDUARDO JIMÉNEZ DE ARÉCHAGA, INTERNATIONAL LAW IN THE PAST THIRD OF A CENTURY (Sijthoff & Noordhoff 1979).....	11
Gary H. Sampliner, <i>Arbitration of Expropriation Cases Under U.S. Investment Treaties—A Threat to Democracy or the Dog That Didn’t Bark?</i> , 18 ICSID REV.-FOREIGN INV. L.J. 1 (2003).....	13
Int’l Law Comm’n, Rep. of the Int’l Law Comm’n, Fifty-Third Session, Apr. 23-June 1 and July 2-Aug. 10, 2001, 56 U.N. GAOR Supp. No. 10, art 4(1), U.N. Doc. A/56/10, Supp. 10 (2001).....	11
<i>Available at http://www.un.org/documents/ga/docs/56/a5610.pdf.</i>	

Kenneth J. Vandeveld, BILATERAL INV. TREATIES: HISTORY, POLICY, & INTERPRETATION (2010).....	12
Kevin A. Hassett and Robert J. Shapiro, <i>What Ideas are Worth: The Value of Intellectual Capital and Intangible Assets in the American Economy</i> (Sept. 2011).....	2
<i>Available at http://www.sonecon.com/docs/studies/Value_of_Intellectual_Capital_in_American_Economy.pdf.</i>	
Letter from Linda Dempsey, NAM, to Susan F. Wilson, Dir. Intellectual Prop. and Innovation, USTR (Feb. 6, 2015), USTR-2014-0025	2
<i>Available at http://www.regulations.gov/contentStreamer?documentId=USTR-2014-0025-0023&attachmentNumber=1&disposition=attachment&contentType=pdf.</i>	
NAFTA Free Trade Comm'n, Notes of Interpretation of Certain Chapter 11 Provisions (July 31, 2001).	14
<i>Available at http://www.state.gov/documents/organization/38790.pdf.</i>	
NAM Policy Positions (approved Mar. 15-16, 2012).....	2
<i>Available at http://www.nam.org/uploadedFiles/NAM/Site_Content/Issues/FINAL%20Policy%20Langage%20Approved%20Winter%202012.pdf.</i>	
Patrick Dumberry, THE FAIR AND EQUITABLE TREATMENT STANDARD: A GUIDE TO NAFTA CASE LAW ON ARTICLE 1105 (Kluwer L. Int’l 2013)	15
Rudolf Dolzer & Margrete Stevens, BILATERAL INVESTMENT TREATIES (1995)	12
Stephen M. Schwebel, Is Neer Far from Fair and Equitable?, Remarks at the International Arbitration Club, London (May 5, 2011).....	15
<i>Available at http://www.josemigueljudice-arbitration.com/xms/files/02_TEXTOS_ARBITRAGEM/01_Doutrina_ScolarsTexts/investment_arbitration/Schwebel_and_fair_and_equitable_treatmente_May_2011.pdf.</i>	
U.S. Dep’t of Commerce, Int’l Trade Admin., <i>Trade Stats Express</i>	1
<i>Available at http://tse.export.gov/TSE/TSEHome.aspx.</i>	
W. Robinson, 1 THE LAW OF PATENTS FOR USEFUL INVENTIONS (1890)	8
<i>Available at http://escholarship.org/uc/item/5w14m675.</i>	

I. INTRODUCTION AND OVERVIEW

1. The National Association of Manufacturers (the NAM) is the largest manufacturing association in the United States, representing businesses of all sizes in every industrial sector and in all 50 states. Manufacturing employs more than 12 million people across the United States, accounting for two-thirds of private sector research and development and contributing \$2.09 trillion to the U.S. economy annually. International trade and investment, and the accompanying international agreements and rules that place discipline and predictability on such trade and investment, are highly important to NAM members and help spur access to new markets, innovation, improved trade and investment relations, and stronger ties overseas.

2. Canada remains one of the most important investment and trading partners for manufacturers in the United States. U.S. manufacturing investment in Canada reached nearly \$110 billion in 2014, more than double the investment in any other country and representing nearly 1/6 of the \$662 billion in U.S. manufacturing investments overseas.¹ Based on the NAM's research and analysis and data provided by the U.S. Department of Commerce, the United States/Canada manufactured goods trade volume totaled more than \$454 billion in 2015, with \$246 billion coming from the export of U.S. manufactured goods into Canada, making Canada the top market for U.S. manufacturing exports.²

3. U.S. manufacturers of all sizes and across all sectors owe a large measure of their success in Canada—and elsewhere globally—to innovation and protection of intellectual property rights. The ability to develop innovative new solutions drives the growth and global competitiveness of U.S. manufacturers. Strong protection and enforcement of intellectual

¹ See Derrick T. Jennings and James J. Fetzer, *Direct Investment Positions for 2014: Country and Industry Detail*, 95 SURV. CURRENT BUS. 7, July 2015, at 13. The U.S. Department of Commerce's Bureau of Economic Analysis provides additional investment data at <http://bea.gov/international/index.htm#iip>.

² U.S. Dep't of Commerce, Int'l Trade Admin., *Trade Stats Express*.

property rights globally is a top international priority for the NAM and its members. According to one study, the value of patents, trademarks, copyrights, and trade secrets to the U.S. economy has risen from \$5.5 trillion in 2005 to more than \$9 trillion by 2011.³ According to this same study, more than 90 percent of the total market value of manufacturers in the pharmaceuticals and biotechnology, telecommunications, automotive, food and beverage, and personal care products sectors can be attributed to their intellectual property.⁴

4. The NAM's policy positions, approved by the NAM Board of Directors, identify international intellectual property protection as a top issue.⁵ The NAM has long advocated that intellectual property laws be applied consistently across all sectors in a manner that is industry and technology agnostic and that strong and comprehensive intellectual property standards be included in global, regional and bilateral negotiations, including in the North America Free Trade Agreement (NAFTA), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and in the recently concluded Trans-Pacific Partnership (TPP). The NAM also works to promote full compliance with intellectual property obligations for all sectors, including annual submissions to the U.S. government's Special 301 Review.⁶ In all of these channels, the NAM has consistently emphasized that strong and reliable intellectual property standards are critical for all manufacturing industries and must be comprehensively and predictably applied.

5. For U.S. manufacturers, intellectual property rights, including patents, are highly valuable property and investments, which is why their protection as investments capable of expropriation under NAFTA is critical to NAM members. Manufacturers of all sizes depend on

³ Kevin A. Hassett and Robert J. Shapiro, *What Ideas are Worth: The Value of Intellectual Capital and Intangible Assets in the American Economy* (Sept. 2011), at 2 ("What Ideas are Worth"). This report is based on data collected by the U.S. Department of Commerce's Bureau of Economic Analysis, available at <http://www.bea.gov/iTable/>.

⁴ *What Ideas are Worth* at 5.

⁵ See, e.g., NAM Policy Positions (approved Mar. 15-16, 2012), Int'l Econ. Affairs Policy ¶ 1.03.

⁶ See, e.g., Letter from Linda Dempsey, NAM, to Susan F. Wilson, Dir. Intellectual Prop. and Innovation, USTR (Feb. 6, 2015), USTR-2014-0025.

patents to protect their investments in research and development centers, manufacturing facilities, and sales and distribution channels. Weak and unreliable patent protections unfairly undermine these investments and the competitiveness and growth of U.S. manufacturers. Protecting patents from undue expropriation and unfair and inequitable treatment ensures that manufacturers with significant capital investments can maintain competitiveness in foreign markets and operate on a level playing field with domestic companies.

6. As part of the NAM's efforts to ensure strong protections for intellectual property rights in all countries, and with Canada being the top investment and trade partner for U.S. manufacturers, the NAM takes great interest in Canadian courts invoking the "promise utility doctrine" to invalidate patents. Although the doctrine has been invoked primarily in the pharmaceutical space, all patents are supposed to be subject to the same utility requirements. If left unchecked, patents in other sectors could be undermined to the detriment of manufacturers. Indeed, the NAM does not view this dispute as a pharmaceutical case but as an issue of broad importance to manufacturers across all sectors. The NAM thus offers its perspective on legal and factual issues in order to assist the Tribunal with three issues implicated by this arbitration.

7. First, given the global nature of today's economy, most manufacturers must secure patent protection in multiple jurisdictions. Manufacturers expect inventions that are new, result from an inventive step, and capable of industrial application will be protected in nations that offer patent protection, such as Canada. This expectation is codified in NAFTA Article 1709.1 and reflects the general practice of developed nations to grant patents that meet these fundamental requirements, as reflected by patent treaties and established patent law canons. The manner in which Canadian courts have revoked patents on utility grounds represents a departure from these expectations and norms.

8. Second, it is established precedent under cases such as *Azinian v. United Mexican States* that judicial decisions are attributable to Canada and that their effect can constitute an expropriation subject to the provisions of NAFTA Article 1110.

9. Third, NAFTA Article 1105(1) incorporates a minimum standard of treatment that is inclusive of fair and equitable treatment (FET) as understood under current customary international law. Thus, Article 1105(1) applies to any state conduct that might infringe a sense of fairness, equity or reasonableness, such as the manner in which Canada developed and invoked its promise utility doctrine to invalidate Lilly's patents. Given the significant investments made by manufacturers in Canada and other countries where they are entitled by investment treaty to FET protections, the FET standard is viewed by the NAM and its members as one of the most valuable protections in NAFTA Chapter 11.

II. CANADA'S PROMISE UTILITY DOCTRINE DEPARTS FROM ESTABLISHED INTERNATIONAL NORMS

A. Overview of How Manufacturers Globally Protect Their Innovations

10. To illustrate how Canada's promise utility doctrine departs from established international norms for patent protection, it is helpful to understand how manufacturers that conduct business globally protect their intellectual property—and how those practices reflect international norms governing the recognition and protection of patent rights. These global practices are discussed below because they reflect broadly established patent protection principles that go part and parcel with NAFTA's patent protection provisions, discussed in Section II.B, *infra*. These practices are not specific to any particular industry or group of industries. A pharmaceutical manufacturer files patents using the same procedures and in accordance with the same fundamental requirements as an automobile manufacturer.

11. When filing patents in multiple jurisdictions, manufacturers frequently file a

single patent application, often pursuant to the Patent Cooperation Treaty (PCT). Signed in 1970, the PCT permits patent applicants from all innovative sectors to file a single patent application in one country. That application is then deemed to have been filed in all PCT member states. Canada, the United States, and 16 other countries were original signatories to the PCT, which now has 148 contracting members. Even when the PCT is not used, manufacturers often file in multiple jurisdictions at the same time to protect novelty.⁷

12. Patent applications in all major jurisdictions consist of three basic components:

- a written specification and drawings describing the invention (often collectively referred to as the patent disclosure),
- proposed claims defining the metes and bounds of the requested patent monopoly (referred to as the patent claims), and
- ministerial documents such as inventor oaths, information disclosure statements listing known prior art, and payment and processing documents.

13. In all patent applications, the patent claims define the scope of the legal monopoly granted by a patent. Patent claims, even when filed under the PCT, are examined and ultimately granted by national patent offices, but disclosures are expected to be substantially the same across all PCT member states. It is widely understood across patent systems and irrespective of the field of the invention that the patent disclosure serves to teach individuals skilled in the technical arts how to practice the patented invention and to provide the public with knowledge in exchange for granting a monopoly for a limited period of time.⁸ Because a patent only provides protection in the nation in which it was issued, manufacturers depend on efficient and consistent processes for protecting inventions globally. Manufacturers will face competitive challenges if they cannot rely on established procedures, such as those defined by the PCT, to protect the same

⁷ Any reference to the PCT is meant only to illustrate customs and norms of manufacturers that internationally file patent applications. Nothing in this submission should be construed as arguing that Canada's actions violate the PCT or other patent-related treaties, such as TRIPS.

⁸ See Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 287-88 (1977).

invention in multiple countries.

14. When filing in multiple jurisdictions under the PCT, the adequacy of the patent application is part of a preliminary examination that occurs before examination in national patent offices, such as the Canadian Intellectual Property Office (CIPO) or the U.S. Patent and Trademark Office (USPTO). Notably, twenty national patent offices (including the CIPO and USPTO) are designated as International Preliminary Examination Authorities (IPEA) with authority “to formulate a preliminary and non-binding opinion on the questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and *to be industrially applicable*.”⁹

15. An IPEA is able to review a patent for industrial applicability because utility is a widely understood patent law concept. In fact, the PCT system depends on having a common understanding and interpretation of such concepts. Manufacturers that file patents internationally thus expect that a patent application disclosing an industrially applicable invention will be sufficient to support claims that are later reviewed and ultimately granted in PCT member states. If applications were held to significantly different industrial applicability standards in different countries, the established international practice of filing a single PCT application would be turned on its head, as manufacturers would need to prepare different disclosures for different nations. It would be hard to internationally protect intellectual property under such a regime.

16. Canada’s actions have also injected uncertainty into Canada’s patent system.¹⁰ A manufacturer should not be afraid that its patent will be invalidated in Canada for not disclosing

⁹ Patent Cooperation Treaty, art. 33, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 (emphasis added).

¹⁰ Nothing in this submission should be interpreted to suggest that Canada is not permitted to invalidate patent claims even when other nations have allowed similar claims, as long as Canada is applying internationally-consistent patentability requirements. Invalid patents serve no economic purpose, and the NAM does not oppose patent invalidations when done on an objective basis. The NAM opposes Canada’s promise utility doctrine because it requires courts to determine whether an invention meets a heightened usefulness test to be worthy of patent protection. That is an inherently subjective inquiry.

a useful invention if that same disclosure is acceptable in 147 other PCT states. Canada's heightened disclosure requirements for utility impose onerous requirements at odds with an efficient global system for protecting intellectual property. If a manufacturer cannot file a single disclosure globally and rely on that disclosure in pursuing patent claims in all PCT member states, it becomes extraordinarily difficult (and for many smaller NAM members, cost-prohibitive) to secure global patent protection.

B. NAFTA Guarantees Baseline Protections for Patents

17. Because many NAM members conduct business in both Canada and the United States, it is important that both countries offer comparable patent protections to promote fair and full access to intellectual property protections in both markets. Many NAM members source product components from one country, assemble finished products in another country, and then resell products in the first country. For example, a NAM member may source inputs from Canada for final assembly in the United States and resale in Canada, while maintaining research and operational facilities in both countries. The NAM thus supported efforts to include intellectual property protections in NAFTA as an important part of that agreement's unified standards to govern and facilitate cross-border commerce. Similarly, NAFTA's protection of intellectual property rights as investments under Chapter 11 is an important baseline in ensuring fairness and predictability in the treatment of intellectual property in the NAFTA countries.

18. NAFTA Chapter 17 sets certain baseline protections for intellectual property. Article 1701.1 states that "[e]ach Party shall provide in its territory to the nationals of another Party adequate and effective protection and enforcement of intellectual property rights."¹¹ A

¹¹ North American Free Trade Agreement, art. 1701.1, Dec. 17, 1992, 32 I.L.M. 605 (1993) ("NAFTA").

nation may provide more intellectual property protection than what NAFTA requires, but it must not provide less protection.¹²

19. One baseline protection in NAFTA is that inventions having *some* utility be protected. Article 1709.1 provides the following guideline:

[E]ach Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms “inventive step” and “capable of industrial application” to be synonymous with the terms “non-obvious” and “useful,” respectively.¹³

20. Usefulness, or utility, is a well understood concept in patent law. Concepts of usefulness were developed and widely understood long before NAFTA and current laws governing patents in Canada and the U.S. There is no basis for NAFTA Chapter 17 to be read in a way that is inconsistent with these understood concepts.

21. Utility is widely understood to be a threshold rather than comparative requirement. In reviewing why patent systems contain utility requirements, patent law historians have observed that “[t]he purpose of the utility requirement is to assure that society obtains a ‘quid pro quo’ . . . before granting a monopoly to an inventor.”¹⁴ Because utility is an objective threshold test, not a subjective comparative test, historically, “[t]o comply with the utility requirement, an invention need not be superior to existing products or processes.”¹⁵

¹² See NAFTA, art. 1702 (“A Party may implement in its domestic law more extensive protection of intellectual property rights than is required under this Agreement.”).

¹³ NAFTA, art.1709.1.

¹⁴ Donald S. Chisum, 1 CHISUM ON PATENTS, § 4.01 (2015) (“CHISUM ON PATENTS”) (citing W. Robinson, 1 THE LAW OF PATENTS FOR USEFUL INVENTIONS, 462-63 (1890) (“ROBINSON”)). Prof. Robinson further observed that the theoretical underpinning of the requirement to disclose a “new and useful” invention is to provide the public with “something. . . which they do not before possess.” See ROBINSON at 109.

¹⁵ CHISUM ON PATENTS, § 4.01. See also *Vornado Air Circulation Sys. v. Duracraft Corp.*, 58 F.3d 1498, 1508 (10th Cir. 1995) (“the framers of the patent system did not require an inventor to demonstrate an invention’s superiority to existing products in order to qualify for a patent”); *In re Krimmel*, 292 F.2d 948, 953 (C.C.P.A. 1961) (“[I]t is our firm conviction that one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans”).

22. By retrospectively testing whether subjective “promises” made in the patent disclosure have been met, Canada has interpreted the patent utility requirement in a way that is new and inconsistent with long-understood notions of utility, including the provisions of NAFTA as well as the understandings that existed at (and long before) the time NAFTA was enacted. This interpretation burdens cross-border commerce by unexpectedly subjecting NAM members to substantively different patent utility requirements in Canada than in other jurisdictions.

23. Holding inventions to different standards and invalidating patents on unexpected bases harms U.S. manufacturers investing and operating in Canada. Intellectual property is a critical form of investment alongside investments in research and development centers, manufacturing facilities, and sales and distribution channels. Manufacturers depend on a stable and predictable intellectual property regime. Canada’s invalidation of patents on unexpected grounds is thus an expropriation of property, as the loss of patent rights leaves an important capital investment unprotected. Put simply, a physical plant can be rebuilt, but once intellectual property is gone, it cannot be replaced: such an expropriation leaves a manufacturer facing unexpected competition, including competition from companies unburdened by the capital investments needed to develop the intellectual property in the first place and little or no recourse or ability to recover those investments.

C. Canada’s Promise Utility Doctrine Creates an Unpredictable and Unstable Regulatory Regime

24. Canada’s promise utility doctrine is also problematic because it confuses patentability requirements with regulatory functions typically administered by public health and consumer protection agencies by asking patent examiners and judges to evaluate whether a patent application discloses an invention that is safe, efficacious, or otherwise beneficial for public consumption. Patent examiners reviewing patent applications and judges adjudicating

patent disputes are experts at administering patent laws and regulations. When examiners or judges also make public health or consumer protection considerations when applying patent laws, as the promise utility doctrine requires them to do, patent laws end up being applied in an unpredictable manner and bring public health and consumer protection scrutiny in an unexpected additional venue, creating an unstable regulatory regime for manufacturers.

25. Because of the threshold nature of the utility requirement, it was well established long before NAFTA that a product that works, albeit relatively ineffectively, can still be patented because “the standards of patentability focus primarily on novelty and not on comparative utility.”¹⁶ As Justice Story explained nearly 200 years ago, concerns over whether an invention meets a certain degree of usefulness or represents substantial improvement over prior art is immaterial to patent law, as the market will diminish a patented invention that is ineffective:

[Respondent argues that] the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. . . . [I]f the invention steers wide of these objections, whether it be more or less useful is a circumstance very material to the interests of the patentee, but of no importance to the public. If it be not extensively useful, it will silently sink into contempt and disregard.¹⁷

26. It was also widely accepted long before the enactment of NAFTA that patent officers neither are, nor should be, arbiters of safety and efficacy.¹⁸ By injecting these concepts into patent law through the promise utility doctrine asking whether the disclosed invention is effective based on the court’s interpretation of the promises made in the disclosure, Canada has subjected manufacturers filing patents in Canada to regulatory scrutiny from an unexpected and inappropriate source. When NAFTA codified the core patentability requirements, the NAFTA parties agreed to a coherent and predictable patentability framework that does not permit raising

¹⁶ CHISUM ON PATENTS, § 4.04[2][a].

¹⁷ *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568).

¹⁸ *E.g., In re Anthony*, 414 F.2d 1383, 1395 (C.C.P.A. 1969) (“Congress has given the responsibility to the FDA, not the [USPTO], to determine . . . whether drugs are sufficiently safe.”).

the bar on utility in a patent context to do the work of other regulatory regimes.

III. JUDICIAL DECISIONS MAY RESULT IN EXPROPRIATION COGNIZABLE UNDER NAFTA ARTICLE 1110

27. The fact that judicial decisions constitute state acts is non-controversial.¹⁹ Indeed, the Tribunal in *Azinian v. Mexico* found that a Mexican governmental decision was not excluded from scrutiny under Chapter 11 simply because the decision had been approved by a Mexican court.²⁰ As such, regardless of whether any specific judicial decision issued by a Canadian court is consistent with Canadian law, that decision is attributable to Canada and will be subject to evaluation of whether it is consistent with Canada's NAFTA obligations. Thus, to the extent that a judicial decision, a regulation, an executive action, or some combination thereof results in an expropriation of intellectual property rights, such an expropriation will be measured against the requirements of Chapter 11.

28. This is particularly true where the judiciary can make law, as the Canadian judiciary has done here in reinterpreting Canada's utility requirement. Canada's promise utility doctrine appears to be the result of an evolution in Canadian courts' interpretation of patentability requirements under Canadian law. That interpretation, as applied to Claimant's revoked patents, is attributable to Canada, and is contrary to the obligations of Chapter 11, which requires that NAFTA Parties do not expropriate an investment without prompt, adequate, and effective compensation.²¹

29. It is of manifest importance to NAFTA country rights-holders that Canada be held to the obligations of Article 1110 with regard to intellectual property rights. Otherwise, by

¹⁹ Int'l Law Comm'n, Rep. of the Int'l Law Comm'n, Fifty-Third Session, Apr. 23-June 1 and July 2-Aug. 10, 2001, 56 U.N. GAOR Supp. No. 10, art 4(1), U.N. Doc. A/56/10, Supp. 10 (2001); EDUARDO JIMÉNEZ DE ARÉCHAGA, INTERNATIONAL LAW IN THE PAST THIRD OF A CENTURY (Sijthoff & Noordhoff 1979) at 278.

²⁰ *Azinian et ors. v. Mexico*, ICSID Case No. ARB(AF)/97/2, Award (Nov. 1, 1999) at ¶¶ 97-105.

²¹ For this reason, it is also irrelevant that the violations of Article 17 are not actionable under Article 1105(3), as interpreted under the Note.

retroactively changing the playing field for investors—subjecting them to fewer patent protections than those which Canada agreed to offer when it acceded to NAFTA—the Canadian promise utility doctrine undermines the fundamental principle of *pacta sunt servanda*, throwing the carefully negotiated and harmonized NAFTA patent system into chaos.

IV. NAFTA ARTICLE 1105(1) REQUIRES FET AS REFLECTED IN CURRENT CUSTOMARY INTERNATIONAL LAW

A. The Status and Operation of FET in International Investment Treaties

30. For the NAM and its members, NAFTA Chapter 11 and other strong investment chapters in trade agreements and bilateral investment treaties (BITs) are critical to advancing the ability of American companies to participate in overseas markets and to promoting greater confidence that their investments will have the degree of protection they need overseas to operate in a predictable and transparent environment.

31. Of the protections provided by Chapter 11, the FET standard is regarded as “the most common general absolute standard of treatment in the BITs.”²² “Nearly all recent BITs require that investments and investors covered under the treaty receive ‘fair and equitable treatment.’”²³

32. The FET standard is a priority for the NAM and its members, as it is viewed as one of the most important protections in NAFTA Chapter 11: it is viewed as a longstanding and basic principle of government behavior towards property, property-owners, and foreign investors. The fair and proper application of this standard by NAFTA members is important to promote the trade and investment relationships envisioned by NAFTA. In establishing this standard in NAFTA and in other agreements, Canada and the United States have long ensured their own rights to pursue public welfare objectives, as long as they do so in a manner that

²² Kenneth J. Vandeveld, *BILATERAL INV. TREATIES: HISTORY, POLICY, & INTERPRETATION* (2010) at § 5.2.1.

²³ Rudolf Dolzer & Margrete Stevens, *BILATERAL INVESTMENT TREATIES* 58 (1995).

protects fundamental rights for investors and investment, much in the way that domestic laws do. While arguments are often made to restrict the interpretation of FET protections, no case has found that a government's generally-applied, non-discriminatory regulatory measure taken in the public interest violates the FET standard and thus would require its limitation. Scholars have also found no cases indicating that the FET standard undermines a government's legitimate right to regulate in the public interest or chills regulatory activity.²⁴

33. FET protections should not be limited in this case, as Canada's actions are not generally-applied non-discriminatory regulatory measures aimed at broadly protecting public health. Such protections should instead be broadly applicable as these actions directly impact specific investments in property. Canada and the United States did not intend to preclude FET claims when the practices of one country depart from established international practices. The NAM respectfully submits that the law governing FET standards has evolved such that actions that violate a sense of fairness, equity and reasonableness, such as Canada's implementing its promise utility doctrine and departing from international patent protection practices, constitute cognizable FET claims.

B. NAFTA Article 1105(1) Requires FET as a Minimum Standard of Treatment of Alien Investments and Investors

34. NAFTA Article 1105(1), as originally adopted, provides that each "Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security."²⁵ Thus, NAFTA Article 1105(1) guarantees FET in accordance with "international law," which is generally

²⁴ See, e.g., Christian Tietje & Freya Baetens, *The Impact of Investor-State Dispute Settlement (ISDS) in the Transatlantic Trade and Investment Partnership* (June 24, 2015); Gary H. Sampliner, *Arbitration of Expropriation Cases Under U.S. Investment Treaties—A Threat to Democracy or the Dog That Didn't Bark?*, 18 ICSID REV.-FOREIGN INV. L.J. 1 (2003).

²⁵ NAFTA, art. 1105.1.

understood to include obligations that are established by treaties and other means.²⁶ Thus, BITs that provide for FET are a legitimate source of “international law.” Three early NAFTA Chapter 11 tribunals adopted this view, finding that NAFTA Parties were required to provide a minimum standard of treatment, inclusive of FET, that reflected current international legal norms.²⁷

35. These decisions fueled questions among NAFTA parties fearful of successful investor claims. Accordingly, in response to these decisions, the NAFTA Free Trade Commission (FTC) issued a binding Note of Interpretation (the Note). The Note states:

1. Article 1105(1) prescribes the customary international law minimum standard of treatment of aliens as the minimum standard of treatment to be afforded to the investments of another Party.
2. The concepts of “fair and equitable treatment” and “full protection and security” do not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens.²⁸

The Note limits the FET (and “full protection and security”) guaranteed by Article 1105(1) to the minimum standard required by customary international law. However, customary international law standards of minimum treatment have evolved to reflect widespread FET practice.

C. Customary International Law Standards Have Evolved

36. Both Canada and the United States have looked for guidance concerning the interpretation of Article 1105 to the 1926 three-page decision issued in *L. F. H. Neer and Pauline Neer (U.S.A.) v. United Mexican States*. The *Neer* Tribunal described treatment violating “customary international law” as “outrage, bad faith, wilful neglect of duty, or an insufficiency of governmental action so far short of international standards that every reasonable and impartial

²⁶ See generally Am. Law Inst., *RESTATEMENT OF THE LAW (3D), FOREIGN REL. LAW OF THE UNITED STATES* (2015).

²⁷ See *Metalclad Corp. v. Mexico*, ICSID Case No. ARB(AF)/97/1, Award (Aug. 30, 2000); *S.D. Myers Inc. v. Canada*, UNCITRAL/NAFTA, Partial Award (Nov. 13, 2000); *Pope & Talbot Inc. v. Canada*, UNCITRAL/NAFTA, Interim Award (June 26, 2000).

²⁸ NAFTA Free Trade Comm'n, Notes of Interpretation of Certain Chapter 11 Provisions (July 31, 2001).

man would readily recognize its insufficiency.”²⁹

37. However, there is little evidence that the *Neer* formulation of the minimum standard of treatment, at the time of its adoption in 1926, definitively reflected widely established state practice at the time, or that states considered themselves obliged to obey the practice (*opinio juris sive necessitatis*). As the Tribunal in *Railroad Development Corp. v. Guatemala* stated, the *Neer* Commission “did not formulate the minimum standard of treatment after an analysis of State practice.”³⁰ For this reason, Judge Schwebel has argued that the *Neer* Commission’s formulation is due only limited weight, noting its “terse, barely reasoned opinion—which examines no State practice at all.”³¹

38. Indeed, multiple tribunals have rejected the notion that *Neer* should be read as reflecting current customary international law. In a decision issued shortly after the FTC’s Note, *Pope & Talbot Inc. v. Canada*,³² the Tribunal observed that “Canada considers that the principles of customary international law were frozen in amber at the time of the *Neer* decision.”³³ That view, which was rejected in the *Pope & Talbot* decision and which Canada again advances here, is without basis. As the *Pope & Talbot* Tribunal observed, “customary international law evolves through state practice,” inclusive of the many post-*Neer* international agreements, such that these agreements now inform what comprises customary international law.³⁴ The Tribunal noted approvingly that the International Court of Justice has moved away from the *Neer* formulation,

²⁹ *L.F.H. Neer & Pauline Neer (U.S.A.) v. Mexico*, 4 R.I.A.A. 60, 61-62 (U.S.-Mex. Gen. Claims Comm’n Oct. 15, 1926). Notably, the *Neer* arbitration did not arise from an investment, but rather concerned state responsibility for the physical security of aliens and conducting investigations into physical violence against such aliens.

³⁰ ICSID Case No. ARB/07/23, Award (June 29, 2012) at ¶ 216. See also Patrick Dumberry, *THE FAIR AND EQUITABLE TREATMENT STANDARD: A GUIDE TO NAFTA CASE LAW ON ARTICLE 1105* (Kluwer L. Int’l 2013) at 17.

³¹ Stephen M. Schwebel, *Is Neer Far from Fair and Equitable?*, Remarks at the International Arbitration Club, London (May 5, 2011) at 4. Judge Schwebel notes that, at the time of the *Neer* decision, Mexico took the position that aliens were entitled to no more than national treatment. *Id.* at 2.

³² UNCITRAL/NAFTA, Award in Respect of Damages (May 31, 2002).

³³ *Id.* at ¶ 57.

³⁴ *Id.* at ¶ 59.

finding that conduct violating minimum standards of treatment need not be such that every independent observer will be “outraged” but may be found in acts that “shock[], or at least surprise[] a sense of judicial propriety.”³⁵

39. Subsequently, in *Mondev International Ltd. v. U.S.A.*, the Tribunal observed that *Pope & Talbot* concluded that “Article 1105 [as revised by the FTC] incorporated an evolutionary standard, which allowed subsequent practice, including treaty practice, to be taken into account.”³⁶ Further noting that the *Neer* case arose in a context wholly unlike that of an investment treaty,³⁷ the *Mondev* Tribunal found it

unconvincing to confine the meaning of “fair and equitable treatment” and “full protection and security” of foreign investments to what those terms—had they been current at the time—might have meant in the 1920s when applied to the physical security of an alien. To the modern eye, what is unfair or inequitable need not equate with the outrageous or the egregious.³⁸

40. The Tribunal also noted that the “vast number of bilateral and investment treaties...almost uniformly provide for fair and equitable treatment of foreign investments, and largely provide for full security and protection of investments.”³⁹ Noting the geographic distribution of these treaties, the Tribunal emphasized “the remarkably widespread basis” in which “States have repeatedly obliged themselves to accord foreign investment such treatment. In the Tribunal’s view, such a body of concordant practice will necessarily have influenced the content of rules governing the treatment of foreign investment in current international law.”⁴⁰ As a consequence, the *Mondev* Tribunal concluded that “the investments of investors under NAFTA are entitled, under the customary international law which NAFTA Parties interpret Article

³⁵ *Id.* at ¶¶ 63, 64, citing *Case Concerning Elettronica Sicula S.p.A. (ELSI)*, 1989 I.J.C. 15, 76 (July 20).

³⁶ ICSID Case No. ARB(AF)/99/2, Award (Oct. 11, 2002) at ¶ 105 (citing *Pope & Talbot*, Award in Respect of Damages (May 31, 2002) at ¶ 59).

³⁷ *Mondev* at ¶ 115.

³⁸ *Id.* at ¶ 116.

³⁹ *Id.* at ¶ 117.

⁴⁰ *Id.*

1105(1) to comprehend, to fair and equitable treatment and to full protection and security.”⁴¹

41. *International Thunderbird Gaming Corp.* confirmed the evolutionary approach.⁴²

The claimant there argued that, “if an investor or investment reasonably relies on the representations of government officials and suffers damage because of such reliance, the responsibility of the State is engaged under international law.”⁴³ The Tribunal agreed with this contention, noting that it was obliged to “measure the Article 1105(1). . . minimum standard of treatment against the customary international law minimum standard”⁴⁴:

Having considered recent investment case law and the good faith principle of international customary law, the concept of “legitimate expectations” relates, within the context of the NAFTA framework, to a situation where a Contracting Party’s conduct creates reasonable and justifiable expectations on the part of an investor (or investment) to act in reliance on said conduct, such that a failure by the NAFTA Party to honour those expectations could cause the investor (or investment) to suffer damages.⁴⁵

Having reached the important conclusion that “denial of reasonable expectations” by a Party is, if proved, a compensable offense under Article 1105(1), the Tribunal further found that the “content of the minimum standard should not be rigidly interpreted and it should reflect evolving international customary law.”⁴⁶

42. Similarly, the Tribunal in *Chemtura Corp. v. Canada* followed the *Mondev* line of thinking, noting that, while “it is not disputed that the scope of Article 1105 must be determined by reference to customary international law[.]. . .[s]uch determination cannot overlook the evolution of customary international law nor the impact of BITs on this evolution.”⁴⁷ The *Chemtura* Tribunal thus determined to take “into account the evolution of international

⁴¹ *Id.* at ¶ 125. Importantly, the Tribunal made the following practical observation: “A judgment of what is fair and equitable cannot be reached in the abstract; it must depend on the facts of the particular case.” *Id.* at ¶ 118.

⁴² *Int’l Thunderbird Gaming Corp. v. Mexico*, UNCITRAL/NAFTA, Award (Jan. 26, 2006).

⁴³ *Id.* at ¶ 138.

⁴⁴ *Id.* at ¶ 193.

⁴⁵ *Id.* at ¶ 147 (internal citation omitted).

⁴⁶ *Id.* at ¶ 194 (internal citation omitted).

⁴⁷ UNCITRAL/NAFTA, Award (Aug. 2, 2010) at ¶ 121.

customary law as a result *inter alia* of the conclusion of numerous BITs providing for fair and equitable treatment.”⁴⁸

43. Thus, numerous Tribunals have rejected Canada’s argument that customary international law remains frozen as of the 1926 *Neer* decision. Rather, customary international law evolves with the practice of states and their sense of legal obligation, as reflected in, *inter alia*, numerous BITs that establish a FET standard that measures state acts by standards broader than those that would violate the *Neer* formulation.

44. Indeed, decisions concluding that *Neer* remains valid rest on questionable grounds. For example, the Tribunal in *Glamis Gold v. U.S.A.* observed that the Claimant had failed to prove that the customary international law standard of the treatment of aliens had changed since *Neer*.⁴⁹ In so doing, however, the *Glamis* Tribunal imposed a more stringent standard for finding a violation than did *Neer*. Whereas *Neer* mentions the criteria of “outrage,” “bad faith,” “wilful neglect of duty,” and “insufficiency of government action,”⁵⁰ the *Glamis* Tribunal embellished these criteria, and would find a violation only where an act was “egregious and shocking,” represented a “gross denial of justice,” and reflected “blatant unfairness,” or a “manifest lack of reasons.”⁵¹ These embellishments go beyond *Neer*, stiffening minimum standards of treatment without evidence that the new restrictions are justified by state practice or *opinio juris*, either presently or as they were at the time of *Neer*.

45. This “stiffening” continued in *Cargill, Inc. v. Mexico*, where the Tribunal held that, to violate the *Neer* standard, government acts must amount to “gross misconduct,” or

⁴⁸ *Id.* at ¶ 236.

⁴⁹ See *Glamis Gold, Ltd. v. U.S.A.*, UNCITRAL/NAFTA, Award (June 8, 2009) at ¶ 627.

⁵⁰ *Neer*, 4 R.I.A.A. at 61-62.

⁵¹ *Glamis* at ¶ 22.

“manifest injustice.”⁵² Similarly, the Tribunal in *Waste Management Inc. v. Mexico* concluded that Article 1105(l) prohibits treatment that is “arbitrary, grossly unfair, unjust or idiosyncratic, is discriminatory and exposes the claimant to sectional or racial prejudice, or involves a lack of due process leading to an outcome which offends judicial propriety.”⁵³ These glosses would appear to minimize states’ obligations in a way that the *Neer* Tribunal did not envision. Notably, the *Glamis*, *Cargill* and *Waste Management* Tribunals do not explain how the practice of states or *opinio juris* has changed to justify such relaxed standards for FET claims.

46. The 2010 decision in *Merrill & Ring Forrestry L.P. v. Canada* is instructive as to why the overly rigid FET standards on which Canada relies should not be adopted here.⁵⁴ Reviewing the history of formulations of the minimum standard of treatment allowable under customary international law, the *Merrill* Tribunal observed that it “is also quite evident that NAFTA jurisprudence has stiffened since the FTC Interpretation.”⁵⁵ Contending that this “stiffening” was misguided, the Tribunal explained that, post-*Neer*, the minimum standard of treatment under customary international law had developed along two tracks.⁵⁶ With respect to the first, which related to minimum standard of treatment with respect to individuals and their personal safety, the Tribunal concluded that “[n]o general rule of customary international law can . . . be found which applies the *Neer* standard, beyond the strict confines of personal safety,

⁵² *Cargill, Inc. v. Mexico*, ICSID Case No. ARB(AF)/05/2, Award (Sept. 18, 2009) at ¶ 286. That said, the Tribunal observed that “the current customary international law standard of ‘fair and equitable treatment’ . . . reflects the adaptation of the agreed *Neer* standard to current conditions.” *Id.* But the Tribunal’s formulation of the “evolved” standard as requiring “gross misconduct” or “manifest injustice”, *id.*, appears to stiffen the prerequisites for finding a violation without a concomitant showing that the practice of states, and their self-perceived obligations, had changed in this manner.

⁵³ ICSID Case No. ARB(AF)/00/3, Award (Apr. 30, 2004) at ¶ 98.

⁵⁴ UNCITRAL/NAFTA, Award (Mar. 31, 2010).

⁵⁵ *Id.* at ¶ 200.

⁵⁶ *See id.* at ¶¶ 204-205.

denial of justice and due process.”⁵⁷ On the other hand, the minimum standard applicable to business, trade and investments reflected a continued and “unabated” liberalization, such that

[a] requirement that aliens be treated fairly and equitably in relation to business, trade and investment . . . has become sufficiently part of widespread and consistent practice so as to demonstrate that it is reflected in customary international law as *opinio juris*. In the end, the name assigned to the standard does not really matter. What matters is that the standard protects against all such acts or behavior that might infringe a sense of fairness, equity and reasonableness.⁵⁸

47. Although the Tribunal in *Merrill* found that the investor had not proven that it was treated by Canada contrary to the requirements of Article 1105(1), that case makes a highly persuasive argument that, in cases involving business, trade, and investments, such as the case under consideration here, claims should not be restricted based on narrow readings of *Neer*. Rather, customary international law has evolved such that the minimum standard with respect to investments and investors requires treatments within the confines of reasonableness. As noted above, *Merrill* convincingly states that “[w]hat matters is that the standard protects against all such acts or behavior that might infringe a sense of fairness, equity and reasonableness.”⁵⁹ That understanding of the FET standard is one that will achieve NAFTA’s vision and promote the investment climate amongst the NAFTA countries that was envisioned.

V. CONCLUSION

48. As discussed above, Canada’s promise utility doctrine is inconsistent with international patent protection norms, and Canada bears international responsibility for that doctrine under NAFTA Chapter 11’s expropriation and FET provisions.

⁵⁷ *Id.* at ¶ 204.

⁵⁸ *Id.* at ¶ 210.

⁵⁹ *Id.*

Respectfully submitted,

/s/

Linda E. Kelly

Patrick N. Forrest

Leland P. Frost

**NATIONAL ASSOCIATION OF
MANUFACTURERS**

733 10th Street, NW, Suite 700

Washington, DC 20001

202.637.3000

Charles Owen Verrill, Jr.

Maureen E. Thorson

Brian H. Pandya

WILEY REIN LLP

1776 K Street, NW

Washington, DC 20006

202.719.7000