MONSANTO v. GOVERNMENT OF CANADA: NAFTA AND THE RBST CONTROVERSY: A CANADIAN PERSPECTIVE

By Kevin Gibson*

Le Chapitre 11 de l’Accord de Libre-échange Nord Américain est probablement devenu avec le temps l’une des portions de l’entente de libre-échange ayant suscité le plus de réactions et entraîné le plus de polémiques, tant au plan juridique que social. À cet égard, le présent article tentera d’examiner la controverse entourant le récent refus de Santé Canada d’autoriser en territoire canadien la vente et la commercialisation du rBST, produit fabriqué par la compagnie Monsanto et autrement connu sous le nom de “Nutrilac”. Décision d’ailleurs contestée par la corporation américaine en vertu des dispositions de l’ALÉNA. Or, le choix par Monsanto et le Canada du mécanisme prévu au chapitre 11 s’explique non seulement parce qu’il est le plus naturel dans un contexte nord-américain de règlement des différends commerciaux, mais aussi, à la lumière d’un examen d’ensemble de l’ALÉNA, parce qu’il est susceptible de fournir assez de souplesse aux parties pour arriver à une entente pouvant satisfaire à la fois la partie privée et publique. Cela dit, pour bien mesurer la portée du chapitre 11 de l’ALÉNA et son impact sur le gouvernement fédéral, il est utile de comparer ici l’affaire impliquant Monsanto avec la récente Affaire du boeuf aux hormones en Europe et dont le différend fut porté cette fois devant l’organe de règlement des différends de l’OMC.

The investment protection provisions of Chapter 11 of the North American Free Trade Agreement† have emerged as the most publicly and hotly debated feature of the agreement, involving a matrix of legal and social issues. This article proposes to examine the controversy surrounding the recent refusal of Health Canada to approve the sale and use of the Monsanto rBST product to be called Nutrilac in Canada‡, and will chiefly be conducted from the perspective of a dispute arising under the provisions of NAFTA. This is done both because the NAFTA text will be an obvious instrument for the settlement of a grievance by Monsanto, or the US government on its behalf, and because a careful examination of the provisions relevant to this dispute will shed light on the structure of NAFTA as a whole, as well as its ability to satisfy the stated goals of its parties. A thorough consideration of this issue also requires evaluation of dispute settlement under the WTO, and the related controversy arising from the recent EC beef hormone case provides an obvious point of comparison in an assessment of the degree to which the NAFTA investor protection paradigm effectively circumscribes federal regulatory power.

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I. Introduction: Economic and Biological Implications of rBST

It is beyond the scope and competence of this discussion to make a sophisticated explanation of the chemical nature of rBST. Yet it is impossible to assess the legal implications of the drug's rejection without understanding the scientific basis for this rejection in the first place. Indeed, it is disagreement over scientific data that lies at the heart of the controversy. Before any veterinary drug can be marketed in Canada, the Food and Drugs Act and Regulations require the manufacturer to submit scientific data demonstrating that the drug in question is safe and effective when used in accordance with the directions on the label. While BST, or bovine somatotrophin, is a naturally occurring protein hormone secreted by the pituitary gland of the cow, the artificial production of this hormone and the effects of its administration to lactating cows require review and approval by federal regulators at Health Canada. Ordinarily, the hormone enters the bloodstream, causing the liver to produce other protein hormones, including insulin-like growth factor-1 (IGF). BST and IGF then reach various cells in the cow's body, some acting directly on the mammary glands to stimulate milk production, others increasing the breakdown of fatty tissue, in turn giving the cow more energy for higher milk production.

The technique developed by Monsanto involves the isolation of the gene responsible for the production of BST which, after a complex process artificially reproducing the hormone, is injected into the cow's bloodstream to enhance milk production by 10 to 15 percent. While there is agreement over the function of rBST in cows, debate surrounds the ancillary effects of the hormone on both the animal and the human population, and this has sparked a heated public debate, as much a political and legal matter as one generated by academic opinion. Although the drug received the approval of the US FDA in 1994, it is no surprise that Monsanto has lobbied strenuously for the approval of its product in Canada: it is estimated that the company spent ten years and more than $150 million to develop and market the product worldwide. Opponents of rBST, in particular the Sierra Club of Canada and the Council of Canadians, are been responsible for much of the ensuing public controversy. Both non-governmental organizations, while interested from a 'health and safety' perspective, raise questions about the legal dimension of Monsanto's activity, and ultimately direct discussion toward the problematic question whether

3 A critical analysis is undertaken in the rBST (Natrelac) "Gaps Analysis" Report of the rBST Internal Review Team, Health Protection Branch, Health Canada. References to the function of the hormone may be found in the reports of the Expert Panel of the Canadian Veterinary Medical Association and the Royal College of Physicians and Surgeons, available at the Health Canada online: <http://www.hc-sc.gc.ca/english/archives/releases/99_03e.htm>.

4 This is particularly important in determining the place of scientific analysis in “risk assessment” for the purposes of NAFTA and WTO SPS provisions, and will be examined below.

5 Food and Drugs Act, R.S., c.F-27, s.30.

6 “Canada’s $8 Billion Dairy Industry Is Awash In Controversy Over Synthetic Growth Hormones” Financial Post (July 1, 1995).
Canada’s sovereign ability to regulate in the areas of health and safety is infringed by the provisions of the NAFTA.

At the request of Health Canada, two panels were established to review the safety and efficacy of rBST\(^7\). The first, organized by the Canadian Veterinary Medical Association, reviewed material provided by Health Canada from Monsanto’s submission, assessing, *inter alia*, animal body condition, udder health, reproduction, lameness, culling and animal welfare. While the Panel concluded that milk yield increased, so too did the risk of clinical mastitis and intramammary infection which present dairy health management techniques could not alleviate, and which may result in an increase in antibiotic residues from the treatment of these illnesses. Lameness was found to increase by 50 percent, and there were several effects on reproductive performance, including a decline in pregnancy, increased risk of cystic ovaries and multiple births. As well, treated cows were at higher risk of being culled. The Panel concluded that there were several legitimate animal welfare concerns related to the use of rBST, and while they concluded that there was sufficient evidence available to make a reasonably informed assessment about the drug’s effects, it was also point out that if Nutrilac were approved for sale, more information would be required in order to manage its detrimental side effects.

At the request of Health Canada, a second panel was organized by the Royal College of Physicians and Surgeons of Canada to examine the pertinent human safety issues. It was charged with reviewing “international scientific reports and conclusions,” and making “observations and recommendations regarding the adequacy of the scientific data submitted” by Monsanto. While it concluded that it “does not believe at this time that there is a significant probability of increased human toxicity resulting from the very small increments in the milk and other products from rBST-treated cows,” it also expressed concern about “the indication that rBST may cause an immune response in rats exposed to high dosages, and recommended that “the sponsor should be asked to repeat the 90 day toxicity studies of rBST and to explore whether there is a real risk of hypersensitivity reactions….” In particular, the panel noted concern about the antibody response observed in a rat treated for 90 days with rBST at a dose of 0.1mg/kg/day, resulting in an antibody response at a low dose after only 14 weeks of exposure.

A repetition of the study in question in the so-called “Gaps Analysis” Report of an Internal Review Team of the Health Protection Branch in Health Canada disclosed both procedural and data gaps which failed “to properly address the human safety requirements of this drug”\(^8\). The question of oral absorption of the hormone had not adequately been addressed, and based on the proposed label supplied by Monsanto, the increased risk of mastitis associated with the use of rBST was found to have human health implications. Finally, the Report noted that the only major country

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\(^7\) References to the findings of the Expert Panels of the Canadian Veterinary Medical Association and the Royal College of Physicians and Surgeons may be found at the Health Canada website (*supra* note 2).

\(^8\) “Gaps Analysis” Report at 3.
allowing the sale of a commercially prepared rBST for milk enhancement was the US. In contrast, Canada, Australia, New Zealand and none of the EU countries had then allowed any rBST product to enter into their respective markets.

II. NAFTA Chapter 11: A Private Right of Action to Enforce Market Access through Investments

Monsanto has already indicated an intention to pursue approval of Nutrilac through the framework of Health Canada regulations. But in light of recent disputes involving the alleged infringement of American investment opportunities by Canadian legislation, it is timely to consider the operation of the NAFTA in this case, and particularly the provisions of Chapter 11 governing investor-state disputes. It has been argued that “[b]usinesses, especially globally oriented ones, increasingly view trade issues and investment issues as being integrally linked within the concept of ‘market access’.” The investor-state dispute settlement provisions of NAFTA Chapter 11 unquestionably extend to investors in a host Party a degree of protection from expropriative action hitherto unknown, and indicate an extension of the traditional method of arbitrating investment disputes, “going well beyond such traditional issues of expropriation and repatriation of profits to include such claims as advertising restrictions, pharmaceutical regulation and commercial contract dispute.” It has even been suggested that the NAFTA, “though an international trade agreement, exhibits characteristics typical of constitutions” in such features as the effective removal of certain subjects from the legislative agenda, a difficulty in amendment through effects which are not easily reversed, and a politically binding nature.”

The related issues of expropriation and compensation are set out in Article 1110. This provision contemplates the treatment of a foreign corporation in the event

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9 Ibid. at 8.
10 Recent and costly disputes have prompted reconsideration by all three parties of actions for “expropriation” or measures tantamount thereto. Canadian and Mexican ministers of foreign affairs and of trade met recently with American trade representative Charlene Barshefsky in the hope of reaching an interpretive note to Chapter 11, narrowing and clarifying the grounds on which companies could bring claims against a Party. According to the Hon. Sergio Marchi, what is sought is “a rider that would put an end to expropriation on an expansive basis, but [would] make sure that the original intent is kept.” Such measures are still awaited. In the meantime a Canadian stakeholder advisory committee on the investor-state chapter identified such options as making a country’s national laws governing expropriation the reference for panels (see discussion of this option below. 

12 Ibid. at 44.
13 D. Schneiderman, “NAFTA’s Takings Rule: American Constitutionalism Comes to Canada” (1996) 46 U. of T. L.J. 499. Schneiderman notes that the taking of investment interests under NAFTA is prohibited by language drawn directly from the American constitutional experience, specifically the incorporation of both the Fifth Amendment law of takings and the Fourteenth Amendment law of due process. He suggests that a troubling political influence by groups or parties contrary to democratic decision making may exist.
of expropriation under special arbitral rules and procedures; but it is important to emphasize the degree to which these provisions extend to a foreign investor a new and stronger protection of capital and standing to challenge government policy in dispute settlement. If the government of a Party, through the passage of laws inconsistent with this Chapter, “directly or indirectly nationalize[s] or expropriate[s] an investment of an investor of another Party,” that investor may demand arbitration and receive “compensation equivalent to the fair market value of the expropriated investment”14. Paragraph 1 forbids any Party from acting to “directly or indirectly nationalize or expropriate an investment of an investor of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment....” Any future discussion of Chapter 11 in light of the rBST dispute must focus squarely on the question whether a mere regulatory undertaking may be construed in a manner to include the refusal by the Canadian government to permit the manufacture and sale of rBST in Canada, and ultimately, whether legislation enacted under the sovereign right of a government to regulate in the areas of health and safety is trumped by a prohibition against expropriation or any act tantamount thereto contained within a trade agreement to which the Party states have assented.

The Chapter 11B dispute mechanism provides that an investor of a Party can submit to binding arbitration a claim that another Party has breached a substantive obligation in Section A15. These provisions contemplate the failure of a Party State to comply with obligations regarding national treatment, the imposition of performance requirements, senior management and board of directors requirements, expropriation and compensation, and transfers relating to investment. These provisions raise several matters which may be relevant in the event of a claim by Monsanto, but the question whether the corporation has suffered an expropriation, indirect expropriation, or a measure tantamount thereto is a controversial matter requiring clarification.

There is little juridical writing examining the way in which the line between permissible regulation and prohibited expropriation (or act tantamount to expropriation) is to be drawn, but some indication of the right balance may be taken from the text itself. The Chapter does not apply to measures adopted or maintained by a Party which are covered by Chapter 14 on Financial Services16. Nor should the Chapter be construed so as to prevent a party from providing services or performing functions such as law enforcement, correctional services, income security or insurance, social security or insurance, social welfare, public education, public training or health and child care, in a manner not inconsistent with Chapter 1117. The Chapter does not make dispute settlement available, either under 11B or Chapter 20, where restriction of or prohibitions upon investments are made pursuant to the National Security exceptions of Article 2102, or where decisions are made under the

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14 Arts. 1110(1), (2).
15 Art. 1116.
16 Art. 1101(3).
17 Art 1101(4) Although this provision has no ‘teeth’, it should at least be taken as an indication of intention in construction.
Canadian Investment Review Act\textsuperscript{18}. Further, the Agreement provides that Chapter 11B should not be construed to prevent a party from adopting, maintaining or enforcing any measure which is otherwise consistent with the Chapter that it considers appropriate to ensure that investment activity is undertaken in a manner sensitive to environmental concerns. Significantly, paragraph 2 states that the “Parties recognize that it is inappropriate to encourage investment by relaxing \textit{domestic health, safety or environmental measures}” (emphasis added). If there is uncertainty over the scope of expropriative measures treated by the Agreement, the following argument will demonstrate that the document, on its face, cannot be read as prohibiting government regulation in health and safety, where a relaxation in this area would otherwise encourage investment. At the very least, to hold that Health Canada's action is expropriation seems to run counter to the spirit of Article 1114.2.

In a Chapter 11 dispute where it is argued that Canada has taken a measure tantamount to expropriation, we argue that the best response - and the most credible in light of other provisions in Chapters 7 and 9 - would be that a proper construction of the NAFTA does not permit the exclusion of legitimate government regulation. The Parties cannot be thought to have intended these provisions to nullify the legitimate power of sovereign governments to regulate under the conditions noted above, but without an explicit meaning given to the term “expropriation,” how would Canada respond to Monsanto before an arbitrator, and under what conditions would it do so?

III. NAFTA Chapter 11: Settlement of Investment Disputes

As we have seen, Chapter 11, Section B, establishes a mechanism for the settlement of investment disputes arising under Section A between a NAFTA Party and an investor of another NAFTA Party through international arbitration. In order to gain standing, the investor must have suffered some loss or damage due to that breach\textsuperscript{19}. Disputing parties are required first to attempt to settle any claims through consultation and negotiation; if unsuccessful, however, an investor must notify a party of its intention to submit a claim to arbitration at least ninety days before submission\textsuperscript{20}. The Agreement provides generally that after six months have elapsed since the events giving rise to the claim, the claim may be submitted to arbitration under:

(a) the ICSID Convention, if the disputing party and the party of the investor are both parties to the convention;

\textsuperscript{18} Annex 1138.2. However, the threshold of review under the Investment Review Act is so high (limited to \textit{acquisitions} over $150 millions, with no review of indirect acquisitions or the establishment of new enterprises) as to render the scope of foreign investment review under the Act useless for all but those acquisitions involving substantial sums, in which case the Canadian government may exercise a power of review, but is not assured of the ability to deny the investment outright.

\textsuperscript{19} Art. 1116.2

\textsuperscript{20} Art. 1118 and 1119.
(b) the Additional Facility Rules of ICSID, if either the party of the investor or the disputing party is a member; or

c) the UNCITRAL Arbitration Rules.21

Because neither Canada nor Mexico are presently signatories to the ICSID Convention, disputes involving these two countries directly will therefore take place under the ICSID A.F. Rules or the UNCITRAL Rules.22

The procedural rules of the selected forum govern the proceedings of the arbitration, except to the extent modified by NAFTA.23 Where NAFTA Rules are silent, however, the procedural rules of the forum selected by the disputing investor govern the arbitration proceedings. Article 1131 provides that a Tribunal shall decide the issues in dispute “in accordance with the provisions of the NAFTA and applicable rules of international law.” However, the interpretation of rules governing dispute over the substantive matter of NAFTA remains unclear.

The Vienna Convention on the Law of Treaties is the first document to consider in treaty interpretation.24 According to Article 31, “a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose.”25 Furthermore, “any relevant rules of international law applicable in the relations between the parties,” for example CEC and Environmental Side Agreement Obligations should be taken into account, “together with the context” of the treaty.26 A premium is therefore placed upon the ordinary meaning of the treaty, as determined on the face of the document itself, and the provisions of Article 1110 must be interpreted first according to such an ordinary meaning. This attitude is reflected in an issues paper produced by the Canadian Department of Foreign Affairs and International Trade, which argues that Article 1110(1)'s coverage of direct and indirect expropriation and measures tantamount to nationalization or expropriation must be construed narrowly, at least to the extent that not every government regulation should be caught: “NAFTA Parties never intended these provisions to limit the legitimate rights of governments to regulate.”27

21 Art. 1120.
23 Art. 1120.2.
25 Vienna Convention on the Law of Treaties, art. 31(1).
26 Art. 31(3).
IV. What is “Expropriation”, “Indirect Expropriation” and “Tantamount to Expropriation”?  

“Ordinary Meaning” is considered in the commentary on Article 1110. The Canadian position has simply been to take the terms “expropriate” and “expropriation” and define them in light of their meaning in common parlance which, with respect to the first term, is “to dispose (a person) of ownership, to deprive of property”; and in the second is “the removal from ownership” or “the action of depriving (a person) of property”. Therefore, for the purposes of the first part of the NAFTA formulation (i.e. “no Party may directly or indirectly... nationalize or expropriate or investment...”) the government would assert that there should be some “taking of ownership”, either directly or, if indirectly, through measures that “although... not de jure or explicitly expropriative, have the same result”.

With respect to “indirect expropriation”, however, the Canadian government recognizes that in certain bilateral investment protection agreements, this term may be understood to have wider application than absolute takings and must be judged on a case-by-case basis. One suggested of limit of this term is that of the 1967 OECD Draft Convention on the Protection of Foreign Property and accompanying Resolution, which gives as examples of indirect expropriation excessive or arbitrary taxation, the prohibition of dividend distribution coupled with compulsory loans, refusal of access to raw materials or of essential export or import licenses. But the persistent problem with such attempts to identify the types of prohibited action is that they do not recognize or affirm the existence of an underlying objective which might save otherwise prohibited action.

The third element of Article 1110 is more troubling. Measures “tantamount to nationalization or expropriation of an investment” may, according to the Canadian government, mean something more than “indirect expropriation” or may merely be redundant: “[g]iven the possible breadth ‘indirect’ expropriation, measures ‘tantamount to’ expropriation may therefore be interpreted by some as having the potential to catch an even wider range of government measures.” While the specific exemption of certain government activity in the area of intellectual property matter in Chapter 17 and with respect to debt securities in Art 1110(3) might lessen uncertainty about the intended scope of the term, the fact that such measures are actually specifically excluded “may give rise to the argument that these words are otherwise to be given a full and unlimited interpretation.” At issue for the government is the risk of undermining legitimate and effective investor protection while it ensures the exclusion of regulatory practices from the same regime “to the extent that they are

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29 Ibid. at 3.  
30 Ibid.  
32 Ibid.  
33 Ibid. at 5.
legitimate and reasonable”\textsuperscript{34}. But we are left again with the problem of defining a legitimate and reasonable regulation. The Canadian government’s position looks to acts which can be justified as lying within the scope of a regulatory power which the Parties intended to preserve:

\textit{The NAFTA Parties never intended the expropriation and compensation provisions... to limit the legitimate rights of governments to regulate, …} [and] customary law recognizes that acts or measures that may have an impact on the value of property rights are not expropriatory where such acts are non-discriminatory and within the normal exercise of a State’s regulatory prerogative.\textsuperscript{35}

How, then, may the existing provisions be interpreted in accordance with the intentions of Party states to preserve a legitimate regulatory function? One way of ensuring that such a function is not thwarted is contemplated by placing on the party disputing the regulation the burden of demonstrating an absence of \textit{bona fides}, or an abuse of governmental powers. This only makes sense where, on their face, regulatory actions of government are considered to be reasonable.

The strongest and most satisfactory argument Canada could advance in the event of a full-blown dispute on the rBST question is that the action of Health Canada regulators does not, on any reasonable reading of the NAFTA and in light of the area in which the regulation is made amount to anything more than a mere regulation, and is not in the nature of any of the three forbidden expropriatory actions. Several arguments to support this position may be made. One commentator has even noted that “modern nationalization do not always take the form of a single legislative act vesting ownership of the alien property in the state... [and] a state may prefer to progressively diminish the share of alien interest in a particular industry,” and gives customs restrictions, taxes, and price and wage controls as examples of such activity\textsuperscript{36}. It would be impossible to assert that all environmental regulation which impinged upon investment, even that which involves the distribution of licences, requires compensation. At international law the concealed act of interference with property rights, “whatever terminology is to be accepted... [is] legal,” and even authority that such an act should be for a public purpose is weak\textsuperscript{37}. Indeed, despite the government’s ability to treat investors in differing circumstances differently\textsuperscript{38}, it has been asserted that the public purpose requirement may merely be an affirmation of

\textsuperscript{34} \textit{Ibid.}
\textsuperscript{35} \textit{Ibid.} at 6. However, even the “non-discriminatory” test is too onerous. Consider that investors, if in different circumstances, do not need to be treated alike; e.g. a softwood lumber agreement distinguishes between investors from different provinces through differing quotas.
\textsuperscript{37} \textit{Ibid.} at 173-4.
\textsuperscript{38} \textit{Supra} note 21.
the requirement of non-discrimination anyway. But has Health Canada acted in such a way as to deprive Monsanto of an investment so as to give rise to a claim for compensation? For the purposes of Chapter 11, investment is defined to include generally “an enterprise” and “interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory.” Yet if expropriation involves a seizure of such an investment, we argue that the regulatory prohibition in question does not belong to that continuum.

It has been argued that interpretation of the concepts of “expropriation” or measures “tantamount to expropriation” “should be influenced by Canadian, American and Mexican jurisprudence [and] in Canada, case-law and academic literature suggest that expropriation extends to tangible and intangible property, including interests in shares of a company and goodwill.” However, the mere loss of property rights resulting from government action may not always amount to an expropriation: “a mere prohibition for instance does not constitute an expropriation from which compensation may be presumed to follow.” Neither Canada nor Mexico has constitutionally enshrined property rights, and Canadian jurisprudence has generally favored an expansive definition of a police power permitting takings, suggesting that the loss of property rights resulting from government action, without more, will not require compensation.

The crucial case to illustrate the distinction between a ‘taking’ and a ‘mere prohibition’ is *France Fenwick and Co. v. R.*, in which the Crown directed a ship to go to a certain place and not to unload without permission. When the ship followed the direction and loss resulted, the Court held that the Crown direction did not amount to a requisition of the ship, even though it involved interference with the use and enjoyment of property. If the Crown were absolutely prohibited by the common law from expropriating without compensation:

> that rule can only apply... to a case where property is actually taken possession of, ...or where, by the order of a competent authority, it is placed at the disposal of the Government. A mere negative prohibition, although it involves interference with an owner’s enjoyment of property does not... carry with it at common law any right to compensation.

In *British Columbia v. Tener* the Supreme Court of Canada extended this doctrine, developing a two-part test by which permissible regulation may be

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40 *Supra* note 1 art. 1138.
42 *Ibid*.
distinguished from impermissible taking. In addition to a deprivation of interest in property, Estey J., for the majority, concluded that there must also be a corresponding acquisition of value by the regulating authority. There, a regulation prohibiting exploitation of park lands without a license an expropriation where such regulation rendered useless a plaintiff’s title to minerals in those lands. The plaintiff’s predecessors had been granted rights to certain minerals on Crown lands, as well as the right to the use and possession of the surface of the lands for the purpose of extracting the minerals, which rights were originally granted by the Crown. As these lands were designated parks, their exploitation and development was prohibited by statute. While title to the minerals present in the lands remained undisturbed, the plaintiffs argued that the regulations denying their ability to exploit effectively expropriated their interest in the minerals, since they were prohibited from access thereto. Estey J. held that the interest transferred from the plaintiffs to the Crown the value of the minerals, and thereby added value to the park, “enhancing the value of the asset.” This element of “enhancement” in value as a necessary component of expropriation where there has been a denial of a license suggests that an expropriation, even widely construed as a “constructive taking,” must include some transfer of value to, or enrichment by the expropriator corresponding to the loss suffered by the plaintiff.

In contrast to the Canadian government’s suggestion that non-discriminatory acts which have an impact on property rights are excluded from NAFTA’s expropriation provisions, it has been suggested that a contextual approach to the interpretation of Article 1110 requires that the terms be given a broad interpretation to include any kind of taking of property. Accordingly, the concept of indirect or constructive taking should be taken to mean an unreasonable interference with the use, enjoyment or disposal of the investor’s property: “Regardless of whether expropriation is broadly or narrowly interpreted, a measure that substantially interferes with an investor’s use of property is clearly... ‘tantamount’ to an expropriation.” It has been suggested that even mere acts which “impair the benefits of NAFTA investors, may be subject to this... obligation.” But the limits to such arguments must be shown, and have not received sufficient attention. Suppose, for example, that a government implemented a regulation prohibiting the spreading of PCB-laden material over the highways of the province: there could be no question that such a regulation would fall within the ambit of the provincial government's competence to regulate in environmental and health-related matters. Why should the decision of Health Canada regarding rBST be treated differently, particularly in light of the questions raised about Monsanto’s testing methods in the Canadian “Gaps Analysis”?

Discussion of the nature of expropriation in Canadian jurisprudence, possesses features not represented in the facts of the Monsanto-Health Canada

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46 Ibid. at 670.
47 Ibid. at 305.
48 Dearden, supra note 41 at 117.
49 B. Appleton, Navigating NAFTA, (Scarab., Ont.: Carswell, 1994) at 86.
dispute. This jurisprudence aims to demonstrate a depletion of value in the subject-matter at issue - whether land, goodwill or money - and a corresponding enrichment in the government resulting from the legislation or regulation. Yet, we argue, there can be no deprivation of a property interest sufficient to amount to an expropriation where Monsanto has merely been forbidden from manufacturing and marketing a material, the safety of which clearly places it within the ambit of government rule-making. It hardly requires mentioning that there would be no dispute if Health Canada were to prohibit the manufacture and general distribution of a *patently* toxic material; why, then should debate follow where such an act is done to a material for which the scientific data suggests not only uncertainty about effects on the human and bovine populations, but outright harm. The government should be permitted to pursue regulation in the grey area of scientific *doubt*.

Comparison with earlier government action which was claimed to violate the expropriation provisions of Article 1110 is instructive. The so-called MMT Fuel Additives case has already received significant attention as the only dispute to date to have proceeded to an arbitral tribunal, and it is thus the only existing (if largely hidden) paradigm for the treatment of expropriation and compensation matters. The disputed action in this case concerned the 1997 Canadian *Manganese-Based Fuel Additives Act*²⁵, prohibiting all interprovincial and international trade in the fuel additive MMT, a gasoline octane enhancer, for which Ethyl Corp. of Richmond, Virginia was the sole North America producer. Although it remained legal to manufacture and market MMT within each province, the interprovincial and international trade ban effectively prevented Ethyl Canada from conducting a substantial portion of its Canadian business, thereby adversely affecting its investment in this country. As an act for the “positive and progressive harmonization of North American fuel standards” and “to protect jobs and consumers from adverse economic impacts, due to increased engineering costs for auto companies”, it was legislation which contemplated both environmental and economic protection. Yet the ban did not mean that the additive was prohibited as a toxic substance under environmental legislation, but merely that its transboundary movement was restricted. The legislation thus both severely interfered with the investment of one foreign-owned firm and produced a benefit to the Canadian auto industry, which opposed the use of MMT on economic grounds. Despite disagreement over the human and environmental effects of the product, to save the legislation through an argument that it achieved a legitimate objective for which NAFTA makes provision was impossible.

Monsanto likely would not have such an argument available to them. It does not appear that the Canadian operations of the corporation have been interfered with

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50 The credibility of the Canadian scientific data will be treated more fully in the discussion of sanitary and phytosanitary regulations, below.
in such a way as to deprive them of the benefits of their investment, giving rise to the “expropriation” or “tantamount to” arguments. To put it crassly, the government has simply said “no”; it has not said “give me that” in such a way as to fall within a reasonable construction of Article 1110. Moreover, it has said “no” in an area where it could not be thought to have surrendered competence to legislate. Finally, it has said “no” in a manner effecting fundamentally different results than those witnessed in earlier disputes.

We argue that at least two conclusions follow and are available to the Canadian government in the event of an arbitrated dispute over expropriation. First, it may contend that there has been no action by it amounting to conduct in the nature of a taking of a proprietary interest as forbidden in the terms “expropriation”, “indirect expropriation” or “measure tantamount to nationalization or expropriation.” Alternatively, it may argue that its regulation, although in the nature of a taking, is saved by the provisions of Article 1114 exempting regulation for the purposes of health and safety, and that any measure in the NAFTA circumscribing such activity could not reasonably have been in the minds of the framers. Either way, it is submitted, the Canadian government might argue persuasively that it retains this legitimate regulatory function within the operation of NAFTA, and that this does no harm to the reasonable protection extended to investors by Chapter 11.

V. NAFTA Chapters 7 and 9: Sanitary and Phytosanitary Measures, Standards - Related Measures and Canada-US Relations after the EC “Beef Hormone Case”

We have until now been considering what direct action Monsanto itself might bring against the Canadian government under the expropriation provisions of Chapter 11. This argument does not, however, contemplate what action the US, as a Party state, might bring against Canada for erecting non-tariff barriers to trade and what answer Canada might make. In its statement of purpose, Chapter 11B explicitly provides that the establishment of a dispute settlement mechanism applicable to investment disputes does not prejudice the rights of Parties under Chapter 2653, and only anti-dumping and countervailing duty matters, covered under Chapter 19, are excluded. It has been suggested that an investor could seek relief under Chapter 11B, in the form of money damages, while the investor's own State sought relief against the other state's practices under Chapter 20, through injunctive relief or other equitable remedies54. Consideration of alternative action taken by the US in a state-state action, either pursuant to the Uruguay Round Agreement on SPS Measures or the Sanitary and Phytosanitary Provisions of Chapter 7 of the NAFTA, is therefore required, as well as the role of Chapter 9 treating standards related measures. In both agreements, a general approach is taken to ensure that SPS measures are taken for scientific purposes, as opposed to measures hiding trade-protectionism (which could

53 Art. 1115.
54 Horlick and Marti at 49.
be said to have existed in the MMT prohibition), and that standards related measures conform to international standards.

The Uruguay Round of Multilateral Trade Negotiations, concluded in 1993, produced an agreement addressing standards relevant to the protection of the environment and public health. The Agreement on the Application of Sanitary and Phytosanitary Measures\(^{55}\) concerned such domestic regulations as those designed to protect the food supply from contamination, and governs measures defined by the objective of the measure and the type of product regulated, principally those that restrict additives, pesticides, and other contaminants in order to protect the integrity of the food supply.

The Uruguay Round SPS Agreement introduced the concept of a WTO member’s appropriate level of sanitary and phytosanitary protection. This term is defined to include “any measure applied... to protect human or animal life or health within the territory of the Member arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs”\(^{56}\). Generated in large part by the serious dispute between the US and Canada with the European Union over hormone-treated beef, this text was designed to prevent the abuse of sanitary and phytosanitary measures as non-tariff barriers to trade, and places scientific tests at its core: measures undertaken by a Member country must be “based on scientific principles and... not maintained without sufficient scientific evidence”\(^{57}\). National measures conforming to international standards, such as those established by the Codex Alimentarius Commission are presumptively valid\(^{58}\). Although the choice of appropriate level of protection belongs to WTO Member state, that level must “take into account the objective of minimizing negative trade effects”\(^{59}\). Moreover, each party is to “avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade”\(^{60}\).

A WTO member state may adopt measures more stringent than international standards to achieve its appropriate level of sanitary or phytosanitary protection, so long as those measures are supported by a “scientific justification”\(^{61}\). Therefore, the member state may adopt measures more stringent than harmonized international standards, but only so long as such measures are grounded in sound science: “[h]owever, it is by no means clear that ‘good science’ can be defined with precision

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59 *Ibid.* at art.5.4.

60 *Ibid.* at art.5.5.

61 *Ibid.* at art.3.3.
in the abstract”62. The Agreement elaborates that “there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of protection”63.

Although this provision appears to clarify the meaning of “scientific justification,” the Agreement is rendered obscure because it ultimately relates a party’s appropriate level of sanitary and phytosanitary protection with the concepts of “scientific justification” and “available scientific information”64. Countries are required to assure that SPS measures are “based on an assessment, as appropriate in the circumstances, of the risks to human, animal or plant life, taking into account risk assessment techniques developed by the relevant international organizations”65, as well as “available scientific evidence”66. Where there is scientific uncertainty or inadequate data “where relevant scientific evidence is insufficient,” WTO member states “may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information”67.

On January 26, 1996, the US lodged a formal complaint with the World Trade Organization over the European Union’s ban on the importation of meat derived from animals treated with growth hormones. The ban, which went into effect on January 1, 1989, had until then resulted in sharply lower US exports of red meat to the European Union which, according to the US Department of Agriculture, cost US producers $100 million annually. The US challenge to the hormone ban was grounded in the argument that it had no scientific basis, caused injury to US livestock producers, and thus violated the 1994 Uruguay Round SPS Agreement on health and safety measures used to restrict imports.

The EU Commission enacted the ban on production and importation of meat derived from animals treated with nontherapeutic growth hormones ostensibly on the ground that it was required to protect the health and safety of European consumers. It is important to point out, however, the presence of other underlying features governing aspects of the trade relationship which do not enter into the question of Canadian regulation to throw it into doubt. Although it is not argued here that the EU was interested in a maintaining protectionist ploy, even a cynical view of the Canadian context could not employ these features to argue that Canada operated from economic considerations. In addition to consumer concerns, political and economic considerations worked in the EU’s Common Agricultural Policy (CAP), under which beef benefited from both high domestic subsidies in the form of price supports and variable tariffs to protect it from import competition in much the same way that the

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63 Uruguay Round SPS Agreement, art. 3.3 n.2.
64 Ibid.
65 Ibid at art.5.1.
66 Ibid at art.5.2.
67 Ibid at para 22.
disputed Manganese-Based Fuel Additives Act served a mixed health and economic purpose. The resulting accumulation of a surplus of beef, costly to store, was relieved by any EU measure limiting beef imports that would create competition with domestic production. Reinforcing consumer concerns and the position of economic and political policy makers, the dramatic conditions created by the outbreak of bovine spongiform encephalopathy in Britain created (however unreasonably) the fear that any tampering whatsoever with the beef supply would discourage the consumer in Britain and in the EU from buying meat. Between 1986 and 1988, the United States attempted to have the ban overturned through the Committee on Technical Barriers to Trade under the Standards Code of the GATT, but was blocked by the EU. When the ban entered into force on January 1, 1989, the US retaliated by imposing tariffs high enough to prohibit $100 million of EU exports to the United States.

As we have noted, the protracted dispute over the beef hormone ban was one reason the US sought stronger rules in the Uruguay Round governing the use of SPS measures to restrict trade. While such provisions are intended as legitimate responses to concerns over food safety or the protection of the health of people, animals and plants, there is concern – and uncertainty – over where such measures enter the realm of trade protectionism and, like expropriation, this problem is both difficult to resolve and particularly important to any action by the US on behalf of Monsanto’s interest in Canada.

In May 1996, the WTO Dispute Settlement Body established a panel to hear the case in response to the US request, and after seeking scientific opinion issued its final report in August 1997. It was determined that the EU ban ignored a vast body of evidence – some derived from their own reviews – that it is safe to consume meat from animals to which growth hormone has been administered. The matter ultimately rested on a finding by the WTO Panel that the EU ban was grounded in sanitary measures not supported by adequate risk assessment, adopted arbitrary or unjustifiable distinctions in the levels of sanitary protection, it considers to be appropriate in different situations which result in discrimination in international trade, and maintained sanitary measures not based on international standards without the justification indicated by the SPS agreement. An Appellate Body subsequently generally reinforced these findings, along with several procedural challenges raised by the EU.

While the Appellate Body upheld the conclusion that the EU’s import prohibition was not based on a risk assessment within the meaning of Article 5.1 of the SPS Agreement, a careful reading of their amendments to the initial Report may suggest ways in which Canadian regulators may avert an adverse ruling. A reading of Articles 5.1 and 5.2 of the SPS Agreement, stipulating the basis for SPS measures in “risk assessment”, and Article 5.5, treating the consistency of levels of protection and resulting discrimination or disguised restriction on international trade is necessary.

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68 A recent estimate by the EU Commission that ending the hormone ban would reduce EU meat consumption by 20% only supports that view.
Article 5.1 of the *SPS Agreement* provides that “[m]embers shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.”\(^69\) According to the initial finding of the Panel, this provision may be viewed as a specific application of the basic obligations contained in Article 2.2, by which any SPS measure is to be “applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.”\(^70\)

Paragraph 4 of Annex A of the *SPS Agreement* defines risk assessment as “the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or foodstuffs”. Risk assessment, as defined by the Panel, was to involve a two-step process that “should (i) identify the adverse effects on human health arising from the presence of the hormones at issue when used as growth promoters in meat..., and (ii) if any such adverse effects exist, evaluate the potential or probability of occurrence of such effects.”\(^71\) There is thus a threshold introduced into the evaluation, making it insufficient that an assessment establish merely *that* an adverse effect exists arising from the substance in question, but demanding that a “higher degree or a threshold of potentiality or possibility” is reached\(^72\). While the Appellate Body rejected the suggestion that a certain magnitude or threshold level of risk had to be demonstrated in a risk assessment in order to support an SPS measure consistent with Article 5.1, it nevertheless held that the term “identifiable risk” could not be applied to the uncertain result of scientific inability to prove that a substance will never have adverse health effects.\(^73\)

What factors, then, are relevant to the determination of risk assessment? Article 5.2 of the *SPS Agreement* provides that “[m]embers shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods.” The Panel stated that for the purposes of the EC measure in question, a risk assessment required by Article 5.1 was to be “a scientific process aimed at establishing the scientific basis for the sanitary measure...” to the extent that all matters not subject to quantitative analysis by empirical or experimental laboratory methods commonly associated with the physical sciences should be excluded from the scope of a risk assessment.\(^74\) However, according to the Appellate Body

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70 Emphasis added.

71 Panel Report, at para. 8.94


73 Appellate Body Report, at 71.

74 Panel Report, para. 8.93.
The risk that is to be evaluated... under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.\textsuperscript{75}

In addition to the discussion relating to the nature of risk assessment, the question whether a minimum procedural requirement exists in Article 5.1 was also disputed. While the Panel recognized that Article 5.1 does not explicitly require a procedural element linking risk assessment to sanitary measure, they nevertheless required “evidence that at least [the country imposing the measure] actually took into account a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as based on a risk assessment”\textsuperscript{76}. The Panel concluded that the EC did not provide any evidence that the studies referred to were actually taken into account by the relevant EC institutions either when the measures were enacted, or at any later time. Such studies therefore could not be considered as part of a risk assessment on which the EC based its measures. But, according to the Appellate Body, such a term merely suggests “some subjectivity which, at some time, may be present in particular individuals but that, in the end, may be totally rejected by those individuals”\textsuperscript{77}. Rather “based on” should be taken to refer to an objective relationship between two elements, viz. a nexus between SPS measure and risk assessment.

Having posited a minimum procedural requirement in Article 5.1, consideration of the substantive issue of whether the EC measures were “based on” a risk assessment follows. The Appellate Body concluded that, while “the results of the risk assessment must sufficiently warrant, that is to say reasonably support the SPS measure at stake..., [w]e do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure”\textsuperscript{78}. While there must be a rational relationship between the measure and the risk assessment, the Panel permits a degree of divergence within the assessment itself, saying that “Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community”\textsuperscript{79}. While it is typical for governments to legislate in response to “mainstream” scientific opinion, “equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources”\textsuperscript{80}. In the end, however, the Appellate Body concluded that the scientific reports must sufficiently warrant the SPS measure at stake, and that the studies produced by the EC did not “rationally

\textsuperscript{75} Appellate Body Report, at 73.
\textsuperscript{76} Panel Report, para. 8.113 (emphasis added).
\textsuperscript{77} Appellate Body Report, at 73.
\textsuperscript{78} Ibid., at 75.
\textsuperscript{79} Ibid.
\textsuperscript{80} Ibid., at 77.
support” the import prohibition. Moreover, the EC limited its risk assessment to an evaluation of the existence and level of risk associated with the administration of the hormone “in accordance with good practice” without further providing an assessment of the potential adverse effects related to non-compliance with such practice. Therefore, by not proceeding to an assessment, within the meaning of Articles 5.1 and 5.2 of the risks arising from the failure of observance of good veterinary practice combined with the problems of control of the use of the hormones for growth promotion, and in light of conclusions reached in all other scientific studies relating to risk, the Appellate Body concluded that no risk assessment reasonably supporting or warranting prohibition of hormone-treated beef existed.

The Canadian dimension of dispute in similar circumstances requires consideration of whether Article 5.1 of the Uruguay Agreement, read in conjunction with Article 2.2, leads to the conclusion that the results of risk assessment sufficiently warrant the SPS measure at stake; in light of the requirement that any such measure is applied “only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence”. Even here, however, Canada would be permitted, under Article 5.7 to adopt a provisional SPS measure “on the basis of available pertinent information,” such as the “Gaps Analysis Report” and the findings of veterinary and human health panels, until additional information is obtained. Indeed, further study was the very thing requested by the human safety issues panel of Health Canada. We argue that on the reasoning presented in the Appellate Body Report, a rational basis exists for Canada to impose an SPS measure “based on” (in the objective sense required by the WTO) an assessment of risk which satisfies the requirements of the Appellate Body that measures which would ban the import of rBST into Canada conform with the scientific conclusions reached in the scientific studies conducted by the Canadian government which would be submitted as evidence before an arbitrating panel.

In light of the Appellate Body’s concession that there need not be “a monolithic conclusion” in a risk assessment coinciding with the SPS measure taken, and that governments may act responsibly on the basis of divergent opinion, we argue that a sufficient degree of scientific uncertainty exists to support such a measure. Furthermore, the conclusion reached by the “Gaps Analysis” Panel in Canada must be contrasted with those of the scientific studies on which the EC relied. There, the Appellate Body disagreed with the conclusion drawn that because the use of the hormone “in accordance with good veterinary practice” did not reveal any risks, abuse of those materials may prove to be “unsafe”. Here, tests were conducted which, using a low dosage in rat, produced an antibody response 14 days into a 90 test period. Meanwhile, serious questions remain as to what results Monsanto would have discovered had it undertaken tests of a greater length.

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81 Appellate Body Report, at 77.
82 That is, a measure to protect human and animal life and health within the territory of Canada from risks arising from an additive, a contaminant and a toxin (per Annex A definition in the Uruguay Round Agreement).
Like the Uruguay Round SPS Agreement, Chapter 7 of the NAFTA contains specific provisions governing SPS measures as a specific category, and which, like the Uruguay Round, encourage the use of internationally agreed standards, declaring that those standards are presumptively valid. By comparison with Uruguay, however, the NAFTA is somewhat more specific about a party’s right to establish its own “appropriate levels of protection”\textsuperscript{83}, and to implement measures more stringent than international standards\textsuperscript{84}. The effect of this textual difference is difficult to gauge, in part because the scientific requirements of Uruguay are mirrored in NAFTA, and should they be interpreted in the fashion of the WTO, would be difficult to satisfy. And because it is for the disputing party to elect either the NAFTA dispute mechanism or WTO arbitration, Canada may never receive the benefit of NAFTA facility to claim that a more stringent standard has been established.

Technical standards, distinct from measures undertaken as SPS measures, have also been used as an essential element of national sovereignty permitting governments to take measures to protect the environmental health of its people. The NAFTA defines standards-related measures (SRMs) in Chapter 9 to apply to all standards-related matters which directly or indirectly affect the flow of traded goods or services. This Chapter opens to Canadian regulators a scope of authority not extended by the Chapter 7 provisions governing an SPS measure. Under Article 904(1), Canada is permitted to adopt, apply and enforce SRMs that relate to the “safety, the protection of human, animal or plant life or health, the environment, or consumers” by prohibiting the import of a good or service from another Party that does not comply with domestic standards. Under this provision, however, Canada may choose its desired appropriate level of protection, adopt disciplines more stringent than international standards and is not required to justify them on the basis of scientific data and analysis, which proved problematic under the Uruguay Round SPS Agreement, and which would complicate a NAFTA Chapter 7 dispute. Under Article 907, a Party may “conduct an assessment of risk [defined in Article 915 as an ‘evaluation of the potential for adverse side effects’]… taking into account… available scientific or technical information.” So long as the fundamental objective is sustained that a difference in Canadian technical standard is grounded in legitimate policy differences, and is not a disguised attempt to discriminate against foreign goods, we argue that Canadian regulators are freed from the burden of demonstrating the onerous scientific justification of Uruguay and Chapter 7 SPS measures, and may use the “Gaps Analysis” Report as the basis for the policy of legitimate discrimination in its refusal to approve rBST.

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\textsuperscript{83} Article 712(2) provides that an appropriate level of protection is “the level of protection… that the Party considers appropriate.” This language is absent in the Uruguay Round Agreement.

\textsuperscript{84} Article 712(1) provides that a Party may “adopt, maintain or apply any sanitary or phytosanitary measure… including a measure more stringent than an international standard, guideline or recommendation.” This language, too, is absent in the Uruguay Round Agreement.
It is too early to confidently and completely assess investor-related and US state action against Canada over the failure of rBST to gain regulatory approval. This task is made more difficult by the scarcity of published arbitration and critical commentary. However, the scope of NAFTA Chapters 7, 9 and 11, as well as of the Uruguay Round Agreement on SPS Measures, contemplates action which would certainly be available either to corporation or to state in the event of an arbitrated dispute, and it is timely that these matters be considered now, particularly in light of the interpretation given to such terms as “expropriation” and “risk assessment” in earlier disputes. Until clarification is achieved among NAFTA Parties concerning the scope of regulatory power retained by governments, we argue that an aggressive defense of Canadian regulatory power may be mounted in a Chapter 11 claim by Monsanto, and that Canada’s refusal to approve rBST in Canada also ought to withstand scrutiny, either as an SPS measure contemplated by Chapter 7, or an SRM in Chapter 9.