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Potential Impact of the TPPA on Public Health and Medicine Policies.

Contents

Executive Summary

- US corporations, from the submissions they have made to the USTR in relation to the Trans Pacific Partnership Agreement (TPPA) will be seeking a variety of protectionist intellectual monopoly privileges likely to inhibit free trade and the national interest in states parties. These include (a) linkage evergreening and (b) longer terms of pro-monopolistic data exclusivity effectively increasing patent terms. From their submissions they will also be seeking to further diminish evidence-based reference pricing systems particularly in Australia and New Zealand despite lacking any democratic mandate to do so. They have also been asking for the inclusion of an investor-state provision.
- Inclusion of an investor-state provision should absolutely be opposed. Giving corporations the capacity to sue domestic governments when, for example, public health or environmental legislation is not to their liking would be irresponsible giving the lessons of the global financial crisis. It is likely that certain elements of the US federal government will oppose such a provision in any event because of the capacity it will bring for foreign corporations to sue the US federal government.
- It is not clear that Australian negotiators and those of other non-US nations in the TPPA will similarly be taking positive instructions to include provisions that benefit their own small-medium enterprises (SMEs)
- One provision that would benefit Australia's SMEs in the generic medicines sector is the capacity to manufacture in Australia for export overseas to jurisdictions where patents have expired early. This is not contrary to TRIPS.
- Australian and non-US TPPA negotiators should request a provision requiring the US FDA safety regulation system have stronger provisions preventing evergreening of drug patents, restrict corporate influence of drug regulators and reward public interest disclosures about fraud on the public purse.
- Australian and non-US TPPA negotiators should demand that the US health technology regulatory system recognise that pharmaceutical innovation can be equally based on scientific assessment of its comparative cost effectiveness as

well as the operation of competitive markets (the latter requiring strong anti-monopoly laws). They should, along with those of other TPPA nations, demand the inclusion of a provision requiring the US to continue supporting such a federal medicines cost-effectiveness advice agency and remove any legislative provisions inhibiting the creation of a federal PBS-type system in the US. This would create a level playing field for the entry of their pharmaceuticals into the US market.

- Australian and non-US TPPA negotiators should argue for a provision that expands the compulsory licensing exceptions that allow drug patents to be broken (with reasonable compensation) in a public health emergency.
- Australian and non US TPPA negotiators should demand that the US federal government pass laws reintroducing the research use exemption that allows public-funded university researchers to experiment with the chemistry of drugs that are in patent without having to pay royalties.
- The TPPA should be negotiated, implemented, and interpreted to safeguard existing state and local level regulatory, tax, and economic development policies, and to support the social, economic, and environmental values that those policies promote

Introduction

This submission examines the extent to which the proposed Trans-Pacific Partnership Agreement (TPPA) may impact on health and medicines policy in the countries parties to the agreement. The background to potential health and medicines-related provisions in TPPA will be discussed. This particularly will include critical analysis of submissions made to the United States Trade Representative (USTR) on the TPPA and on the 301 Trade Watch list in relation to these issues by US health and medicines corporations and industry bodies. Some of these submissions request (a) “linkage evergreening” provisions, (b) data exclusivity protections that undercut compulsory licensing capabilities and (c) changes to scientific reference pricing schemes concerning the cost-effectiveness of medicines, none of which are required by the

World Trade Organization (WTO) Trade-Related Intellectual Property Rights (TRIPs) agreement. They also seek investor-state rights of corporations to sue the states concerned if their investments are impeded. The submission concludes with an examination, examples and analysis of the potential impact on domestic health and environment should investor state provisions be included in the TPPA.

Background to the TPPA health and medicines provisions

In recent times provisions in bilateral and multilateral trade agreements have allowed corporations to challenge medicines and health care regulation in other nations. The so-called investor-state provisions that appeared in the 1994 a trilateral trade agreement between the US, Canada and Mexico commonly referred to as the *North American Free Trade Agreement* (NAFTA), as will be discussed later, had this effect.[1] So too did the *Australian-US Free Trade Agreement* (AUSFTA) under which the US sought changes to Australia's Pharmaceutical Benefits Scheme (PBS) with a system involving scientific assessment of the cost-effectiveness of medicines as a precursor to government reimbursement.[2] Intellectual property protections are a monopolistic privilege and their place in free trade agreements seems anomalous. Equally problematic are provisions in trade agreements that try to alter the domestic health and environmental policies of other nations with seeking democratic support for such changes (through for example a popular vote or referendum on such changes).

In December 2009 the United States (US) Congress was formally notified by Trade Representative Ron Kirk that the US would enter negotiations for the *Trans-Pacific Partnership Agreement* (TPPA).[3] The United States (US) already has bilateral FTA's

with many of the countries likely to be involved: Singapore, Chile, Peru and Australia.[4] Vietnam, Peru and New Zealand announced that they also would join the negotiations. The first formal round of TPPA negotiations was held in Melbourne on 15-19 March 2010, with the participation of over 200 officials from Australia, the US, New Zealand, Chile, Singapore, Brunei, Peru and Vietnam. Major issues flagged as likely to be discussed in future include: (a) Financial Services (b) Investor-State Dispute Settlement (c) Ways to approach regulatory coherence in the TPP (d) How to ensure small-medium corporate enterprises (SMEs) are able to benefit from the TPPA.[5] Each of these areas, as we shall see, has the capacity to impact of the capacity of the countries involved to regulate health and medicines policy. The ostensible US aim in the agreement appears to be to extend tariff reductions (but enhance protectionist intellectual monopoly privileges) throughout the Asia-Pacific region.[6] Australia's overt ambitions appear relate to shifting the focus in trade negotiations from bilateral to multilateral arrangements where the balance of interests of the parties involved are more likely to be equably expressed in the final text.[7]

Health and medicines policy-related submissions to the USTR on the TPPA

The Pharmaceutical Research and Manufacturers of America (PhRMA) has made a submission to the USTR inquiry on the TPPA. Members of PhRMA frequently interchange employment with those in the USTR, so such submissions are often a useful insight into what the USTR will be placing on the negotiation agenda in that sector. PhRMA is a highly influential lobby group representing the powerful pharmaceutical industry with over 600 lobbyists in Washington.[8] [9] [10]

US pharmaceutical industry seeking changes to Australian and New Zealand medicines cost-effectiveness systems

The PhRMA submission to the USTR on the TPPA suggests that the negotiations "could serve to address "…market access barriers, remedy inadequate consultative mechanisms and transparency concerns in countries like New Zealand, for which no US FTA currently exists…[in doing so] this would ensure that patients throughout the TPP region receive safe, effective and innovative medicines."[11]

This is coded industry/trade-speak which means, in effect, we want to replaced Australia's PBS and New Zealand's Pharmac evidence-based, scientific cost-effectiveness evaluation systems with a market-based approach in which multinational corporations with market dominance can set whatever prices they feel appropriate.

Australia and New Zealand, amongst the TPPA nations have a four-tiered approach to medicine regulation. They consider the safety, efficacy, quality[12] and *cost-effectiveness* of medicines[13]. South Korea, which may eventually become a TPPA member, fought for the capacity to create a PBS-style system during its recent trade negotiations with the USA. This is an important distinction between the Australian and New Zealand government positions and that of PhRMA on medicines regulation. During negotiations for the *Medicare Prescription Drug Improvement and Modernization Act* PhRMA was successful in inserting provisions temporarily preventing federal cost-effectiveness assessment in the PBS method. President Obama has signalled he hopes to remove such an obstacle to federal cost-effectiveness assessment of new health technologies in the US. We will see that PhRMA goes into

more specific details about its wish to alter these aspects of the medicines policy of other developed nations in its 301 Watch List submission.

Novartis, an American pharmaceutical company also lodged a submission with the USTR on the TPPA. In its submission Novartis iterates the sentiment of PhRMA in hoping that the TPPA could promote "cooperation among TPP signatories to ensure the quality, safety and efficacy of medicines" and that the TPPA could lead to "enhanced cooperation among the TPP participants' respective drug authorities" as a way of preventing the entry of substandard medicines onto the market. There is again no mention of cost effectiveness as a tier of regulatory consideration. Novartis also sought (a) provisions in the TPP that would require, as conditions of marketing approval, that a drug manufacturer provide certification of compliance with Good Manufacturing Practices (b) the formation of a Medical Devices and Pharmaceuticals Working Group on issues affecting drug quality, safety and efficacy including in the area of post-marketing pharmacovigilence (c) a private sector advisory and (d) that the Republic of Korea and the Kingdom of Thailand as future participants of the TPP.[14]

Medicines-related IP provisions and the TPPA

The PhRMA submission to the USTR on the TPPA states:

> "A lack of commitment to protect US IP around the world could impair future R&D investment and could discourage the capital investments... A strong IPR framework should not be undermined by other government pricing and regulatory mechanisms that significantly devalue IP protection, or in some cases render it of little economic value."[15]

In their TPP submission PhRMA also claim that they "welcome the opportunity to meet with the US Government TPP team to discuss how our priority issues can be addressed in the TPP negotiations."[16]

PhRMA's 301 Watch List

PhRMA have already identified to the USTR Special 301 report some key intellectual property protection and market access concerns with the governments of Chile, Peru, Vietnam, New Zealand and Australia all of whom are or may become TPPA members.[17] PhRMA has recommended that they all be placed on a special 301 'watch list'. Section 301 of the *Trade Act* of 1974, as amended (19 U.S.C. § 2411), is the principal statutory authority under which the United States may impose trade sanctions against foreign countries that maintain acts, policies and practices that violate, or deny U.S. rights or benefits under, trade agreements, or are unjustifiable, unreasonable or discriminatory and burden or restrict U.S. commerce. The 301 Watch List is often derided as a marketing tool of US multinational corporations, whose ambitions to grab global profits never seem to stoop to measuring human rights or public health and environmental concerns as motivations for the legislation and policies they are impugning. Nevertheless it does give valuable insights into what USTR negotiators might be after in the TPPA.

Chile

According to PhRMA's 301 Watch List submission, Chile, has failed to establish an adequate system to protect proprietary pharmaceutical data required by the US-Chile Free Trade Agreement Article 17.10.2.[18] In particular PhRMA consider that Chile has not moved far enough to protect patent linkage and data exclusivity requirements.[19]

Neither of these is required by TRIPS, but the US has attempted to impose them via a string of bilateral trade agreements (in so-called "TRIP-plus" or "TRIPS-minus" measures depending on your point of view). Patent linkage is an 'evergreeing' technique under which prescription drug quality, safety and efficacy regulators are required to notify a patent holder of an impending generic market entrant (presumably so the patent holders can take steps can be taken to protect their monopoly). Data exclusivity extends the periods where drug safety data which would normally be made available to generic companies upon grant of a patent is kept secret. It purportedly can be used to prevent or inhibit generic products or even compulsory licensing claims to allow patents to be cracked for rapid mass production of medicines in a public health crisis. Data exclusivity is 5 years under the AUSFTA but has already blown out to 15 years in the US. PhRMA claims that a new sanitary decree issued by the Health Ministry for public comment in April 2008 would, if enacted, definitively foreclose linkage by stating explicitly that the Public Health Institute lacks authority to consider intellectual property– or any other criterion apart from safety and efficacy – in granting sanitary registrations.

Vietnam

PhRMA argues that "Even with the significant reforms Vietnam has undertaken in recent years, there are still several areas which are of great concern to PhRMA, namely weak intellectual property protection, the absence of data exclusivity, patent linkage legislation, overly-stringent product registration and clinical trial requirements, a lack of legal status, and government reference pricing."[20] The failure to implement data exclusivity protections is said to be contrary to paragraphs 5 and 6 of Article 9 of Chapter II of the *U.S.-Vietnam Agreement on Trade Relations*. On the

evergreening tactic of patent linkage Vietnam has run the sensible argument that it is not for drug safety authorities to check patent status: “Vietnam argues that it is not appropriate to inject patent enforcement procedures into regulatory procedures, and that it is impossible to issue administrative rules or procedures to administrative agencies to enforce patents.” PhRMA is also upset that Vietnam’s system of Certificate of Pharmaceutical Product (CPP) or a Free Sales Certificate (FSC) and Good Manufacturing Practices (GMP) certification from the country of manufacturing or packaging is mandatory as part of the marketing authorization process for all imported pharmaceutical products. The Vietnamese Government also requires quality tests for all new batches of vaccines and biological products before they are imported into the country. Vietnam’s Law on Pharmaceuticals, passed in June 2005, requires that multinational companies conduct local clinical trials prior to registration of medicines.

Peru

PhRMA has also demanded that Peru have a 5 year data exclusivity provision and the evergreening patent linkage system.[21] The United States and Peru signed the U.S. – Peru Trade Promotion which PhRMA does not consider a model for future trade agreements. The Andean Court of Justice (ACJ) issued several legal opinions (89-AI 2000, 01-AI-2001 and 34-AI-2001) forcing Andean Community members to refuse recognition of patents for second uses. PhRMA is protesting against these.

New Zealand

PhRMA's main concern with New Zealand, is that like Australia, Germany, the Netherlands, Denmark, and British Columbia it has a system for government reference pricing and reimbursement for pharmaceuticals. This system is widely respected as provided a scientific rather than marketing mechanism for assessing whether a ne pharmaceutical produce provided "health innovation" –that is, an improvement in the comparative cost-effectiveness over existing products. PhRMA says,

"The Government of New Zealand remains the primary purchaser of pharmaceuticals in New Zealand. New Zealand's Pharmaceutical Management Agency (PHARMAC) continues to impose stringent cost containment strategies, and operate in a non-transparent, unpredictable manner, creating an unfavourable environment for innovative medicines…Government Reference pricing mechanisms have been introduced in several countries, including Germany, the Netherlands, Denmark, New Zealand and British Columbia. Under reference pricing, medicines are grouped into clusters with therapeutically similar properties. The funder sets a single reimbursement price for all products in a cluster. In New Zealand, in order for a product to receive a subsidy, the price of the product must equal the subsidy;. [22]

Australia

About Australia's medicines system PhRMA states: "PhRMA and its member companies are concerned that: (1) Actions during the ongoing implementation of the AUSFTA have weakened intellectual property provisions; and (2) Existing and emerging issues affecting patient access to new medicines have not yet been adequately addressed.

PhRMA admits it welcomed the "reforms" to Australia's Pharmaceutical Benefit Scheme (PBS) that occurred under the Howard Australian Government. These impeded reference pricing by fracturing the PBS formulary into a patented and a generic medicines class with limited capacity to do scientific comparison of the cost-effectiveness between them. PhRMA member companies and their Australian affiliates (Medicines Australia) continue to monitor the implementation of the PBS reforms and seek to work through a range of remaining issues with the Australian Government. PhRMA states that it "remain[s] committed to ensuring that Government policies adequately recognize and reward innovation." This is industry language for seeking more regulatory changes that protect the monopolistic power of patented medicines companies to charge whatever price they feel like.

PhRMA states that it "continues to be deeply concerned by actions taken by the Australian Parliament after the negotiation of the FTA which weaken and undermine intellectual property provisions that were agreed to during the negotiations." PhRMA is here protesting about Australia's anti-evergreening legislation that was passed at the urging of the Australian Labor Party (which then had control of the Senate) as a condition of AUSFTA implementation legislation coming into force. PhRMA also does not like the mechanism chosen by Australia to implement the linkage-evergreening obligation. The USTR's office after the second meeting of the Australia-U.S. Medicines Working Group, indicated that the anti-evergreening amendments to Australian law appear to discriminate against a field of technology in violation of Australia's WTO TRIPS Article 27.1 obligations. Such penalties, PhRMA claims, are not applicable to patent enforcement actions involving non-pharmaceutical products. This is a spurious argument, because the amendments fall within existing WTO law by being designed to deal with the problem of

evergreening' that only occurs in one industry sector. The legislation was also voted on as a precondition to Australia agreeing to the AUSFTA. To repeal that legislation now would call into question the legal and democratic basis of the AUSFTA. PhRAMA also protests against the possibility of that the Australian *Patents Act 1990* will be amended to allow the manufacture of generic medicines for export to international markets where relevant patents have expired. This is despite the fact that such manufacture does not contravene TRIPS. Including such a provision in the TPPA would in fact create a large boost for the struggling generic industry in the countries involved. PhRMA also claims that Australia's data exclusivity protections are weak, although they are precisely what is required by the AUSFTA and are not required by TRIPS.

Other potential areas of health and medicines policy in the TPPA

The TPPA will not just consider the relationship that can be fostered with the pharmaceutical industry, other industries will be vying for a slice of the Asian-Pacific market. Philip Morris (PM), the tobacco company, lodged a submission with the USTR about the TPPA.[23] It outlined some of its key trading concerns and objectives including its concern over Australia's consideration of a move toward plain packaging of cigarette packets. In September 2009 Senator Steve Fielding introduced the *Plain Tobacco Packaging (Removing Branding from Cigarette Packs) Bill* 2009 to parliament.[24] In addition, the 'Working Group of the Preventative Health Taskforce' convened by the Federal Minister for Health and Ageing, recommended that the government mandate plain packaging for cigarettes. PM believes that plain packaging of cigarettes, a proposal recommended to the Australian government by if adopted by

the government would amount to expropriation of intellectual property rights. In its submission to the USTR PM argues that plain packaging would

> *"…limit the freedom of commercial free speech, significantly restrict competition and breach Australia's obligations under the WTO TRIPs Agreement. Given, on the one hand, the lack of evidence that plain packaging will achieve its intended public health objectives and on the other hand, the wide range of effective measures to reduce smoking incidence, plain packaging is neither an appropriate nor proportionate step to address smoking related issues."*[25]

Investor-State Provisions, Health policy and the TPPA

The multinational tobacco company Phillip Morris (PMI) has argued that an investor-state provision should be included in the TPPA.

"Notwithstanding PMI's general support for the TPP initiative, we are very concerned about the excessive legislative proposals pending in Australia and Singapore that threaten to violate existing bilateral and multilateral agreements with the US. Legislative efforts that undermine international investment, TBT and IP rights in these countries, could complicate the task of negotiating a high standard, 21st century agreement that provides economically significant market access opportunities to America's worker, farmers and businesses. PMI has made significant investments in many countries, including the identified US TPP partners. For that reason, we believe strong investor protections must be a critical element of the TPP and any future US Free Trade Agreements. PMI supports the inclusion in the TPP of an investor state dispute settlement mechanism. The strong investment chapter of the …US-South Korea Free Trade Agreement should be used as a model for negotiating a similar

chapter in the TPP. PMI considers that availability of an investor state dispute settlement mechanism including the right of investors to submit disputes to independent international tribunals, a vital aspect of protecting its foreign investments." [26]

Investor-state privisions have now become a controversial part of over 2000 bilateral investment treaties. [27] Such provisions go beyond those requiring foreign companies be treated no less favourably than a national company (national treatment) and foreign companies be provided with a 'minimum standard of treatment.' They provide authority for those corporations to sue for compensation against a country that may, in the course of regulating for example public health or environment protection problems, directly or indirectly impair an investment.[28] The NAFTA investment chapter (Chapter 11) for example effectively gives foreign investments and investors in host countries an enforceable standard of treatment which included national treatment, most-favoured nation treatment, fair and equitable treatment and full protection and security, restrictions on performance requirements, freedom to designate senior management and boards of directors, freedom to transfer funds, and protection against direct or indirect expropriation.[29]

An example of an investor-state provision is found in the South Korea-US FTA (KORUSFTA), chapter 11. This prevents direct or indirect appropriation of a foreign investment except: (a) for a public purpose (b) in a non-discriminatory manner and (c) on payment of prompt, adequate, and effective compensation. Article 11.8 3(c) provides exceptions:

"Provided that such measures are not applied in an arbitrary or unjustifiable manner, and provided that such measures do not constitute a disguised restriction on

international trade or investment, paragraphs 1(b), (c), and (f), and 2(a) and (b), shall not be construed to prevent a Party from adopting or maintaining measures, including environmental measures: (i) necessary to secure compliance with laws and regulations that are not inconsistent with this Agreement; (ii) necessary to protect human, animal, or plant life or health; or (iii) related to the conservation of living or non-living exhaustible natural resources.[30]

In terms of public health this may mean that governmental bans on alcohol or tobacco may results in a lawsuit from a foreign investor/manufacturer of those products. Despite the government arguing that the bans are for the public interest and the public health, the investor may argue that the ban serves no public purpose and in fact would equate to an expropriation of their profits for which they should be compensated. With respect to the privatisation of a state-run health care system, under a multilateral agreement like the TPPA, if a state monopoly enterprise is privatised, the privatisation must be available to both domestic and foreign investors and therefore health care could move from domestic control to foreign control.[31]

Investor state provisions in international trade treaties, as mentioned, grant investors covered by provisions with a right to initiate dispute settlement proceedings against foreign governments in their own right under international law. These disputes often arise over the interpretation of rights and obligations under the relevant instruments.[32] Where once only an investor's sovereign could bring a claim for damage against a trading partner, now a private actor has the ability to do so.[33] This power extends to not only contesting the validity of the legislation but because claims must be evaluated, there are no limits to the number of claims that may be brought against a government party to the agreement. As such the state is no longer the sole legal

personality in international fora and in some agreements there is no requirement for matters to first be attempted to be resolved at the local level.[34]. Public health matters include and overlap with environmental and labour issues and includes pollution, regulation of tobacco, alcohol and extends to universal health care.[35]

In theory it is thought that an effective and compulsory international dispute settlement mechanism should allow for a balance between domestic political pressures and the interests of foreign investors.[36] It has also been argued however that this type of provision allows foreign investors leverage to undermine legitimate measures that may be made by domestic governments to promote their domestic needs with respect to areas such as sustainable development, environmental protection, and human health and safety.[37] These provisions can pitch private investor rights against public interest.[38] It has been argued that whilst in theory the parties' positions may appear equal, in reality it is often the less developed country that carries the risk of being sued under investor state provisions.[39]

Examples of Health and Medicines Policy-Related Investor-State Claims

Uruguay's tobacco regulations and Phillip Morris

In Uruguay, Philip Morris tobacco has filed an investment treaty claim against that government's introduction of tobacco regulations. It lodged its request for arbitration of the matter with the International Centre for Settlement of Investment Disputes (ICSID) in February 2010. In this case, Philip Morris has its operations centre in Switzerland. The Swiss and Uruguay governments have a bilateral trade agreement. The case highlights the problems with reconciling investment treaty protections and public health regulation by governments. The government wants to remove

misleading marketing descriptors like “light” and “mild”. The company argues that this has resulted in a restriction on for example its Marlboro line. Marlboro Red will remain but Marlboro Gold, Blue and Green have been withdrawn. The government has also legislated for 80% of cigarette packaging to include a public health warning. Philip Morris argues that the size of the warnings prevents trademarks being effectively displayed. Philip Morris is seeking not only compensation for its losses but also the suspension of the regulation.[40]

Canadian chemical regulation and Chemtura

In 2002 the Canadian government had an action brought against it by a chemical manufacturer, Chemtura (formerly Crompton Corporation), because of concern over an indirect expropriation. The Canadian government wanted to introduce legislation that would ban the chemical Lindane which is allegedly responsible for causing several health conditions including developmental disability and hormone disruption, immune system damage and nervous system damage and which is banned in 50 countries. Chemtura disputed these health findings and were able to launch an action for $100 million as a result of the investor state provisions in the NAFTA because the otherwise legitimate Canadian regulation would significantly reduce the value of Chemtura’s property rights. Chemtura went further and in the alternative argued that Canada wasn’t in fact banning Lindane for health reasons but rather for trade reasons. The US forbids the use of pesticides on canola and therefore Canada was required to ban it in order to trade its canola to the US. Further to this, US canola growers complained that the Lindane substitutes that they were required to use in lieu of Lindane was more expensive and therefore gave Canadian growers an unfair competitive advantage. These arguments raised doubt as to whether the Canadian

government was acting in the public interest or to avoid a contractual obligation (or both).[41]

NAFTA investor-state claims against Canadian health and environment regulation

It has been suggested that approximately 40% of legal challenges made under NAFTA's chapter 11 provisions have been against Canadian governmental policy on health and environment.[42] Further examples include Canada's payment of $13 million to the Ethyl Corporation because Canada banned the importation and interprovincial trade on the suspected neurotoxin, MMT.[43] Even if the evidence of MMT's detrimental health effects was not certain, wasn't it right of the Canadian government to err on the side of public health protection as against possible trade destruction? Sun Belt Water Inc. challenged British Columbia's water protection legislation and voluntary ban on exports because they violated Article 1102 National Treatment and 1105 Minimum Standards of Treatment. The company was asking for $10.5 million in compensation but the Canadian government dismissed the claim saying it was invalid.[44] In 2006, the Ontario government rejected a new rubbish tip proposal which had met with overwhelming public opposition and would have had significant environmental impact. The investor in the project, V.G. Gallo lodged a claim of $355 million in expropriation costs.[45] On August 25, 2008, Dow AgroSciences LLC, a U.S. corporation, served a Notice of Intent to Submit a Claim to Arbitration under Chapter Eleven of the NAFTA, for losses allegedly caused by a Quebec ban on the sale and certain uses of lawn pesticides containing the active ingredient 2,4-D.[46]

Canadian health care regulation and Centurion Health

Centurion Health is asking for $160 million as compensation from British Columbia for anti-competitive behaviour. Canada has a universal health care system but Centurion has

argued a Chapter 11 claim that "Canada is an unfair competitor in ways detrimental to US private sector companies in [its] monopolized health care system."[47]

US medicines regulation ad Apotex generic pharmaceuticals

But the claims haven't been all one sided. Canada has brought a claim against the US. Under Ch. 11 provisions of NAFTA, Apotex Inc., a Canadian pharmaceuticals corporation, has alleged that U.S. courts committed errors in interpreting federal law, and that such errors were in violation of NAFTA Article 1102 (national treatment) and Article 1105 (minimum standard of treatment under international law). Apotex also alleged that the challenged U.S. court decision in favour of the Pfizer drug company expropriated Apotex's investments in generic versions of the antidepressant Zoloft under NAFTA Article 1110 and was manifestly unjust.[48] Apotex relied on the doctrine that a manifestly unjust domestic legal decision breaches international law and can be viewed as a substantive denial of justice.[49] Aptoex also argues that the United States had 'no public purpose' for interfering with its property rights and is asking for $8000000 in compensation. Apotex has also brought a similar claim involving US regulatory provisions concerning an abbreviated new drug development application for Pravachol and patents allegedly held by Bristol Myers Squibb.[50] In 2000, a NAFTA tribunal ruled that Mexico violated the trade agreement and ordered the government to pay 16.7 million dollars to the U.S.-based Metalclad corporation. The company had wanted to open a hazardous waste treatment and disposal site in central Mexico but despite some Mexican officials indicating the project could go ahead the local government said the project violated environmental protection laws and refused to give permission for development of the facility.[51]

Californian gasoline regulation and Methanex

Another claim involved the Canadian-based company Methanex, which filed against the United States claiming that the state of California's decision to phase out the use of its gasoline additive, MTBE, cost the company 970 million dollars. Methanex claimed that there was insufficient evidence to demonstrate that MTBE was a carcinogen and that it had contaminated the California drinking supply. The claim however was dismissed and in 2005 Methanex were ordered to pay the United States' $4 million in legal expenses. [52] However California's governor at the time, Gray Davis, ordered the use of MTBE halted after studies revealed unusually high - and potentially harmful - levels of MTBE in California's drinking water. He said, "NAFTA Parties should reopen and renegotiate the provisions of Chapter 11, to ensure the ability of national and sub-national governments to protect their citizens and the environment from toxic substances."[53]

Contemporary US controversy about Investor-State Provisions

During the presidential campaign the Pennsylvania Fair Trade Coalition (PAFTC) a collective who work for 'socially, economically and environmentally just trade policies' asked presidential candidate Senator Barack Obama the following questions to which he answered both in the affirmative;-

> Q:"Will you commit to renegotiate NAFTA to eliminate its investor rules that allow private enforcement by foreign investors of these investor privileges in foreign tribunals and that give foreign investors greater rights than are provided by the US Constitution as interpreted by our Supreme Court thus promoting offshoring?"
>
> Q:."Will you commit to renegotiate CAFTA and the other FTAs now in effect to eliminate their investor rules that allow private enforcement by foreign

> investors of the FTA investor privileges in foreign tribunals and that give foreign investors greater rights than are provided by the US Constitution as interpreted by our Supreme Court thus promoting offshoring?"

And further to this point Obama added:-

> "With regards to provisions in several FTAs that give foreign investors the right to sue governments directly in foreign tribunals, I will ensure that foreign investor rights are strictly limited and will fully exempt any law or regulation written to protect public safety or promote the public interest. And I will never agree to granting foreign investors any rights in the US greater than those of Americans. Our judicial system is strong and gives everyone conducting business in the United State recourse in our courts. The tribunal system was created to ensure that our investors would have access to similar protection abroad. I understand the concerns surrounding this issue, and am committed to working to address them."[54]

The US has also drafted an alternative trade agreement model -Bill H.R 3012 - otherwise known as the "*Trade Reform, Accountability, Development and Employment Act of 2009*" (TRADE Act).[1] This has not yet been signed by the President and does not include Australia as a major trading partner. However, an analysis of the Bill suggests that many of the concerns raised by Australia and other nations in negotiations with the US would be addressed if this legislation were adopted. Amongst other things the Bill reasserts the WTO Doha Declaration on TRIPS (Trade Related Intellectual Property Rights) and Public Health (adopted by the US in 2001). Doha affirmed the primacy of public health considerations over intellectual property protection for medicines. The Trade Reform, Accountability,

Development and Employment Act (TRADE) outlines the following principles for trade agreements with respect to investment provisions:-

> *Trade agreements should preserve the ability of each country that is a party to the trade agreement to regulate foreign investment in a manner consistent with the needs and priorities of the country;
> *allow each country that is a party to the trade agreement to place prudential restrictions on speculative capital to reduce global financial instability and trade volatility;
> *and ensure that no country be subject to an investor-state dispute settlement mechanism under the trade agreement.[55]

The TRADE Bill incorporates the following intellectual property and investor state considerations: [56]

- "That an assessment of the impact of intellectual property provisions of a trade agreement on the retail price of pharmaceuticals within a country that is party to the agreement will be undertaken and any change in the price of pharmaceuticals and the effect that would have on access by consumer to medicines will be considered.
- That each country will be able to adopt and implement environment, health and safety standard that recognise the legitimate right of governments to protect the environment, public health and safety.
- That no agreement will require the privatisation or deregulation of public services, including services related to national security, social security, health, public safety, education, water, sanitation, other utilities, port and will not

limit non-discriminatory national, regional or local governments programs that establish reimbursement rates under public health insurance programs or otherwise control the costs of pharmaceuticals or medical devices."

Australia's response to Investor-State provisions in the TPPA

Australian Minister for Trade Simon Crean made a public statement doubting the value of including investor state provisions in the TPPA. We support this.

> *"It is wrong to suggest that we are about to re-open obligations in relation to the Pharmaceutical Benefits Scheme that were settled in the 2005. If there are to be any changes to the scheme in the future, it would be part of a domestic policy debate in Australia. It does not concern me what the US drug companies are pushing for because decision about the scheme are made in the national interest by the Australian Government. The article also argues there is a threat to Australia from the introduction of an investor-state dispute settlement provision through the TPP. We will give our negotiating partners a chance to pitch their case on the issue, but let me say we have serious reservations about the inclusion of investor-state dispute settlement provision in this agreement. We do not want new layers of red tape under the guise of trade liberalization. Australian negotiators will make this clear at the Melbourne meeting which concludes today.*[57]

Conclusion

The Pharmaceutical Research and Manufacturers of America (PhRMA) submissions for the TPPA show that PhRMA will be urging the USTR in the TPPA negotiations to seek a variety of provisions that are monopolistic and protectionist in nature. They

relate to intellectual property and to a desire to tie up the drug regulatory agencies of other nations in red tape to facilitate the profit-making of US multinationals. Amongst the specific provisions mentioned above as possible PhRMA targets in the TPPA negotiations are linkage evergreening, data exclusivity and reference pricing.[58] There is no justification under TRIPS for such provisions to be sought. The US may have been able to leverage such provisions in the unequal negotiations that characterized in prior bilateral negotiations at a time when a much more corporate submissive US government was in power. Hopefully times have changed. Many commentators in the have questioned the worth of the TPPA deal.[59]

In the TPPA negotiations the USTR is likely to encounter strong resistance from Australia and New Zealand against any inclusion of their medicines cost-effectiveness assessment systems. Further, the days when the US negotiators could turn up to such negotiations hoping to insert provisions altering the health and medicines regulatory systems of other nations but leaving their own alone have gone. There is now a substantial movement in the US for federal level- cost-effectiveness assessment of medicines. Australia, for example, is entitled to demand reciprocal changes in US health care and medicines policies. We should require the US FDA safety regulation system have stronger provisions preventing evergreening of drug patents, restrict corporate influence of drug regulators and reward public interest disclosures about fraud on the public purse. We should demand that the US system recognise that pharmaceutical innovation can be equally based on scientific assessment of its comparative cost effectiveness as well as the operation of competitive markets (the latter requiring strong anti-monopoly laws). The other TPPA nations, for example could demand the inclusion of a provision requiring the US to continue supporting such a federal medicines cost-effectiveness advice agency and remove any legislative

provisions inhibiting the creation of a federal PBS-type system in the US. This would create a level playing field for the entry of their pharmaceuticals into the US market. Non-US TPPA negotiators should argue for a provision that even if a drug is in patent in their countries can be manufactured for sale in other TPPA countries where it is out of patent. The TPPA should expand the compulsory licensing exceptions that allow drug patents to be broken (with reasonable compensation) in a public health emergency. Non US TPPA negotiators should demand that the US federal government pass laws reintroducing the research use exemption that allows public-funded university researchers to experiment with the chemistry of drugs that are in patent without having to pay royalties.

The TPPA should be negotiated, implemented, and interpreted to safeguard existing state and local level regulatory, tax, and economic development policies, and to support the social, economic, and environmental values that those policies promote.[60]

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