Bilateral trade agreements as drivers of national and transnational benefit from health technology policy: implications of recent US deals for Australian negotiations with China and India

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This article compares controversial health technology provisions in two important United States free trade agreements with developed nations: Australia and with South Korea. It examines the multinational corporate forces behind the medicines and medical devices components of these texts and their likely impacts upon Australian trade negotiations with China and India. It also examines the implications of some recent changes to US trade policy for this area in subsequent bilateral deals such as that with Peru. This article argues it is important that the Australian government change policy and, like the present Congress in the United States, now systematically approach such impending trade agreements with a view to assisting the partners’ regulatory frameworks to maximally enhance national and transnational benefit from their medicines and biotechnology industries.

Introduction

The recent Australia-United States Free Trade Agreement (AUS-FTA) was the first time a part of what is officially termed a free trade agreement (FTA) was used to facilitate multinational corporate lobbying pressure to alter a core component of another developed nation’s system for scientifically valuing and correspondingly rewarding (by government price subsidy) the ‘health innovation’ of new pharmaceutical products. The case has elsewhere been made that Annex 2C and various intellectual property protections in Chapter 17 of the AUS-FTA arose as a result of prolonged and successful interaction between US trade negotiators and the U.S patented pharmaceutical industry (Faunce et al. 2005; Senate Select Committee 2004). While AUS-FTA Annex 2C does not contain any explicit provisions requiring this, evidence exists that principles and structures thereby established, eventually facilitated (due to acquiescence by an
Australian government with control over both Houses of Parliament) Australian legislation fulfilling an explicit agenda of US negotiators to reduce price referencing within the Australian Pharmaceutical Benefits Scheme (PBS) (Faunce 2007a). The pro-monopolistic and anti-free trade role of the so called TRIPS-plus provisions in Chapter 17 is equally controversial, but was less unique (Faunce and Lexchin 2007).

Korea has also just entered into an FTA with the US (KORUS-FTA). This text contains provisions on pharmaceuticals similar to Annex 2C and an intellectual property chapter with so-called TRIPS-plus provisions similar to Chapter 17 of the AUSFTA. While some concessions were gained, these are widely regarded as containing even more burdensome and intrusive obligations upon Korea’s domestic regulation of medicines and medical devices than the AUS-FTA placed on Australia. The KORUS-FTA medicines chapter targets proposed Korean drug price formularies in a similar manner to the PBS. It does this, however, whilst more specifically excluding corresponding obligations on the US states. It also achieves an even clearer articulation of policy and regulatory preference for patented medicines over generic pharmaceuticals. It specifically includes medical devices (unlike AUS-FTA Annex 2C).

Australia is currently negotiating an FTA with China yet pharmaceuticals and health technology have so far not been included in briefing documents or talks. This is remarkable given that China is predicted to become the second largest producer of pharmaceuticals by 2020 and already produces a substantial proportion of the active product ingredients (APIs) for Australian pharmaceuticals (Zhou 2007). Given the growing size of China’s generic pharmaceutical industry and Australia’s comparative advantage in regulatory, niche drug discovery and clinical trials expertise, it is reasonable to suppose that the inclusion of a pharmaceuticals chapter and some protections for generics in the intellectual property chapter would greatly benefit both parties. This is certainly also true of the looming FTA negotiations between Australia and India (given India’s growing importance in the global biopharma sector) (Lofgren 2007).

This article analyses and compares the pharmaceuticals and IP provisions of the AUS-FTA and KORUS-FTA through an examination of the negotiations leading up to the agreements, the final texts, and their present and likely impacts on domestic health technology policy. The extent to which each party’s developed and fulfilled goals on health technologies in these trade agreements will be considered, as well as the extent to which changes in the US approach to medicines provisions in trade agreements will influence their subsequent amendment or operation. The article will also examine strategies by which Australia can strengthen its national benefit from health technologies in trade negotiations with China and India.
Background to the AUS-FTA Medicines Provisions

This initial section seeks to examine how the Australian government came to agree to including key aspects of its domestic medicines policy in what, it will be argued, is actually a preferential trade deal. This background to the PBS will form the foundation for a comparison in the following section of the relevant provisions in the KORUS-FTA and the AUS-FTA. In negotiating the pharmaceuticals chapter of the AUS-FTA, US negotiators insisted attention be paid to the PBS, particularly its drug price subsidy mechanisms. In order to understand the FTA negotiations and resulting text, it is therefore necessary to consider the functioning of the PBS and the agenda on medicines policy apparently taken by the Australian trade negotiators.

The PBS

Australia’s PBS is highly respected nationally and internationally as a successful articulation of a scientific approach to ensuring maximum public benefit from government expenditure on medicines. Now solidly based on principles of the National Medicines Policy, it has been operating for over half a century to provide evidence-based, cost-effective and equitable access to healthcare for Australians (Department of Health 2007a). The success of the PBS pricing and listing mechanisms can partly be appreciated through lower average pharmaceutical prices for the government compared with other developed countries (Australian Government Productivity Commission 2001). It is also popular with the public as listed medicines are available for a relatively low co-payment of approximately AU$30 (Department of Health 2007b).

The low costs of medicines are achieved through the PBS pricing and listing mechanisms, parts of which were radically amended in mid 2007. (Faunce 2007a) Before a new patented drug is listed, it must obtain safety, quality and efficacy marketing approval from the Australian Therapeutic Goods Administration (TGA). Once this is done, the supplier may apply to have it listed on the PBS by an independent statutory committee – the Pharmaceutical Benefits Advisory Committee (PBAC) set up under the National Health Act 1953. The PBAC is required to consider applications against certain criteria set out in the legislation. The PBAC cannot recommend a new drug for listing if it is ‘substantially more costly than an alternative therapy’ unless it ‘provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies’ (National Health Act 1953 (Cth), section 101(3B(a)))). Working through a hierarchy of evidence, the PBAC and its advisory subcommittee assess the cost-effectiveness of the submitted product against its best already marketed comparator. If the product is deemed not cost-effective, in a cost-minimisation exercise its price is referenced down to that of the comparator. Reference pricing, in its most fundamental sense, then applies post-listing when new competitors (with lower prices) enter six groups presently
established under the Therapeutic Group Premium (TGP) Policy. In this TGP system, the unusual criterion of ‘individual interchangeability’ assisted patients wishing to obtain an alternative to a drug in one of these groups whose price has a high additional premium.

If the PBAC recommends against listing a particular pharmaceutical, the manufacturer can still access the market and promote its product, however the patient will have to pay a higher out-of-pocket price. The PBS process is thus not a non-tariff barrier to trade. It also facilitates a more science-based approach to pharmaceutical pricing. The Pharmaceutical Benefits Pricing Authority (PBPA) uses the PBAC recommendation to negotiate a maximum amount the government will reimburse to pharmacists (Sansom 2004). It is an evidence-based system of evaluating pharmaceutical ‘health innovation’ on the basis of objectively demonstrated therapeutic significance, in line with the four main objectives of Australia’s National Medicines Policy (Department of Health 2007c):

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

Approaches to medicines in the negotiations

The US position to ‘eliminate’ PBS reference pricing through the AUS-FTA negotiations was part of a legislated agenda. For example, §2102(b)(8)(D) of the (US) Bipartisan Trade Promotion Authority Act of 2002 lists, as one of its principal negotiating objectives, ‘to achieve the elimination of government measures such as price controls and reference pricing which deny full market access for United States products.’ US negotiators had for some time worked closely with senior members of the US patented-pharmaceutical industry on the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3) to develop draft AUS-FTA provisions that would achieve this end. (Industry Functional Advisory Committee 2004) The philosophical position expressed in public to ostensibly explain this stance was that reference pricing in the PBS allowed the Australian government to ‘free ride’ on US research and development (for example see Shiner 2004). Although this free market ideology is little supported by facts and ignores the scientific basis of PBAC evaluations (Lexchin and Light 2005), as will be shown, it is still influential in US policy and has strongly influenced the KORUS-FTA.

The Australian government, on the other hand, had a much more defensive approach to medicines in the AUS-FTA negotiations. It stated that the major concern for its negotiators to the AUS-FTA was to be simply the preservation of
the PBS. Stephen Deady, Australia’s chief negotiator highlighted this passive approach in stating:

...we went into these negotiations with an absolutely clear mandate to protect and preserve the fundamentals of the PBS. That is what this agreement does ... there is nothing in the commitments that we have entered into in Annex 2C or the exchange of letters on the PBS that requires legislative change (Deady 2004).

The Senate Select Committee report stated that most submissions to its inquiry were explicitly against the PBS being a part of such trade negotiations. Its report cited statements from some members of the US Congress who clearly considered that trade negotiations should not be used to interfere with national health systems of other countries, and that domestic health policy should not be a part of any trade agreements (p. 102). The Senate Select Committee concluded that ‘as a core social policy in Australia, the PBS should never have been on the negotiating table’ (p. 102). The committee also noted that although the Australian public was assured that the PBS was never going to be on the negotiating table, there is evidence to suggest that it was an issue from the very first round of negotiations or ‘discussions’ (p. 103). Yet, having been surprised the US had sought and succeeded in including the PBS in the negotiations, Australia, though clearly entitled to do so, sought no corresponding changes at all in US medicines regulation, even despite the tactical advantages this might have produced.

There is also evidence to suggest that in preparing to negotiate the intellectual property chapter 17 of the AUS-FTA, Australian-based stakeholders in the generic pharmaceutical industry were not consulted with anything like the care and detail utilised by the US in the IFAC-3 system. (Faunce 2007b). This is particularly evident in light of the apparent ready acquiescence by Australian negotiators to some of the chapter 17 TRIPS-plus patent term extensions, data exclusivity and ‘linkage evergreening’ provisions which directly opposed the commercial interests of the Australian generics industry.

The PBS in Annex 2C

Australian negotiators, as mentioned, claimed that they went into negotiations ‘with an absolutely clear mandate to protect and preserve the fundamentals of the PBS.’ (Senate Select Committee 2004, p105). The resulting agreement, however, as encapsulated in Annex 2C, contains provisions which (if implemented in legislation) could directly impact the policy and function of the PBS. Three out of four of the Agreed Principles in Annex 2C, for example, mention the need to recognise and promote ‘innovative pharmaceuticals,’ although this term is not generally taken to refer to generic medicines which provide significant cost savings to the PBS (Annex 2C 1(a), (c), (d)).
Despite its manifest importance, the term ‘innovative’ lacks an express definition in the AUS-FTA text. The Annex 2C text allows the word to be interpreted either through the US position of ‘competitive markets’ (so-called ‘market-valued innovation’) or the Australian position of ‘adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical’ (so-called ‘evidence-based health innovation’). The potential for conflict arising from this was recognised by the Senate Select Committee and by others since (Senate Select Committee 2007, p. 107; Faunce et al. 2005). Annex 2C’s statement of agreed principles has also been criticised for not mentioning equitable and affordable access to medicines as encapsulated in the Australian Medicines Policy, as well as being required by the Doha Declaration on the Trade Related Intellectual Property Rights Agreement (TRIPS) Agreement and Public Health to promote public health by facilitating access to affordable medicines (WTO 2001).

The ‘transparency’ provisions under Annex 2C.2 contain requirements that listing PBS proposals are completed within a specified time, that procedural rules, methodologies, principles, and guidelines used to assess a proposal be disclosed, and that applicants are given opportunities to provide comments. These obligations are imposed only on Australia. Australia, as mentioned, sought to impose no reciprocal requirements on US authorities. Furthermore, PBS applicants and the public are to be provided with detailed information about the determinations made, and an ‘independent review process’ is to be available to an applicant directly affected by a recommendation or determination. The legislative form that this review process took framed it more as a quality assurance exercise for PBAC decisions, with no new evidence and no overturning of PBAC decisions permitted (Harvey et al. 2004, p. 257; Faunce 2005).

Annex 2C also establishes a ‘Medicines Working Group’ (MWG) which is to ‘promote discussion and mutual understanding of issues relating to this Annex’ (Annex 2C 3(b)). This has been viewed as creating the potential for patented pharmaceutical companies to lobby for or against existing medicines policies, thereby diminishing the growth of the generics industry (Faunce 2007b, p. 4), for example, through the role of Medicines Australia, the lobby group representing the ‘innovative medicines industry in Australia’ in influencing MWG members.

Although Australian representatives maintained that this group will not influence policy formulation, there is evidence from the first two MWG meetings that specific Australian legislative reforms that would support the US ‘competitive markets’ approach to valuing pharmaceutical ‘innovation’ were encouraged. After the first meeting of the MWG in Washington, in a press conference at the office of the US trade representative in Washington, Australia’s trade minister Mark Vaile stated that:
the core principle that we both agree on in this area and that is recognising the value of innovation and the importance of ongoing innovation as far as pharmaceuticals are concerned as the fundamental central principle in what we’re doing. We continue to monitor a number of different areas in the operations of our system in Australia, our PBS, or as you call it here in the United States, our formulary (Vaile 2006).

This is best interpreted as a statement supporting Australia’s position on ‘health innovation’ in Annex 2C: that it is best determined scientifically by evidence of objectively demonstrated therapeutic significance, rather than by the operation of so-called ‘competitive markets’ (Faunce 2007b, p. 5).

Implications for PBS and Australian health policy

The impacts of the AUS-FTA on national medicines policy and the PBS can arguably now be clearly seen. In August 2007 (after minimal parliamentary debate lasting no more than two week for both houses combined), the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007 was passed, amending key provisions of the National Health Act 1953. In implementing what have been called ‘in substance, the Medicines Australia policy proposals’ (Faunce 2007b, p. 6) for changes to the PBS reference pricing system, the legislation effectively creates two PBS pricing formularies. F1 comprises single brand, mostly patented and ‘innovative’ drugs and F2 comprises multiple brand, mostly generic medicines. Reference pricing no longer occurs between the two formularies (Faunce 2007a). The pricing of new ‘innovative’ medicines in the F1 formulary risks diminishing the extent to which the PBS processes now can be said to be based on objectively demonstrated therapeutic significance (Faunce and Lofgren 2007). In outlining the changes late last year, the Australian Health Minister admitted that ‘Generics Medicine Industry Association is not, as I understand it, especially happy with these changes’ (Abbott 2006).

Although explained as derived from the need to allow lower cost generic medicines into Australia, (Abbott 2006) these F1–F2 legislative changes to the PBS appear to substantially reflect the position on the PBS articulated by US negotiators during the AUS-FTA negotiations (and in the AUS-FTA MWG) on ‘innovation’ in Annex 2C of the AUS-FTA described earlier (Faunce and Lofgren 2007). This suggests that although assurances to the contrary were given, the US policy on the ‘elimination’ of PBS reference pricing mechanisms has been successful to a significant degree, in altering a core aspect of the Australian national medicines system.

A comparison of medicines provisions in the AUS-FTA and the KORUS-FTA

The pharmaceuticals chapter of the KORUS-FTA is described by the US Trade Representative as ‘a shared commitment on access to innovative medicines’
(USTR 2004). It is recognised as having been modelled on Annex 2C of the AUS-FTA, but has been described as even more restrictive (Flynn and Palmedo 2007). The main issues seen to impact medicines, and thus the areas which have garnered criticism, are the restrictions on formulary pricing, and the intellectual property provisions, which are seen to go beyond what is accepted under the TRIPS agreement. However, the KORUS-FTA can also be seen to have broader implications for Korean medicines and health technologies policy.

**Medicines and medical devices**

While the AUS-FTA Annex 2C is entitled ‘Pharmaceuticals’ and deals exclusively with this, the equivalent KORUS-FTA provision is entitled ‘Medicines and Medical Devices’ (chapter five). This broad category is defined in article 5.8 as “pharmaceutical, biologic, medical device, or diagnostic products” and potentially encapsulates much more than its Australian equivalent, by including expensive ‘medical devices’ which could range from cochlear implants to nanotechnology in health care.

**Restricting drug formularies**

Korea announced its intention to create a ‘positive list’ for government reimbursement of the price of pharmaceuticals in May 2006. This move met by strong opposition from KORUS-FTA US negotiators who refused to attend a Pharmaceutical and Medical Device Working Group meeting. In a public statement by a US trade representative, the US saw the decision to create the list as ‘inconsistent with both the mandate of the Pharmaceutical Working Group and the market-opening spirit of the FTA’ (Cutler 2006). In reality, the US negotiators had been surprised that a developed nation had adopted a similar approach to themselves and sought to use FTA negotiations to fulfil its own national interests in medicines policy.

This is not the first time that the US has used trade negotiations with Korea to impose higher drug prices. Since 1999, the US has been negotiating market access in the pharmaceutical sector with Korea (USTR 2004b). One aspect of the negotiations was to pressure Korea to adopt the “A-7 pricing system” for all new innovative medicines, which is the average ex-factory price in the A-7 countries – US, UK, Germany, France, Italy, Switzerland and Japan (USTR 2004b, p. 168). This pressure had been widely criticised, as the result required Koreans to pay much higher prices relative to their average income per person than any of the other A-7 countries. Furthermore, Korea also paid more for patented drugs than the US did in absolute terms (Flynn and Palmedo 2007).

Korea’s mooted drug price reimbursement system is to be part of its universal National Health Insurance (NHI) system, which relies heavily on its generics industry to control the costs of medicines. It is likely to be quite similar to the
Australian PBS in that it uses a formulary (referred to as a ‘positive list’) and reference pricing – aspects which the US also saw as barriers to trade (Flynn 2007a).

Article 5.2 of the KORUS-FTA deals with the issue of pharmaceutical innovation in a somewhat similar manner to Annex 2C of the AUS-FTA. In determining price reimbursements, the KORUS-FTA requires a Party’s determination must be ‘based on competitive market-derived prices’ (article 5.2(b)), (which can be viewed as the US’ preferred position) or if it is not, the Party must then ‘appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides.’ The crucial focus in this context must be on the word ‘value’. It is likely that the Koreans will argue, after they have set up a science-based positive list formulary like the PBS, that the term ‘value’ in this alternative must mean something different than “competitive market-derived prices.” As such it would be a legitimate expectation that it referred to a process of evidence-based determination of ‘objectively demonstrated therapeutic significance’ as mentioned in AUSFTA Annex 2C.

Article 5.2 of the KORUS-FTA allows the use of comparators in pricing (in allowing manufacturers to apply for an increased amount of reimbursement based on relative safety or efficacy (article 5.2 (b)(ii)). There is, however, no explicit support for pre-AUS-FTA PBS model of reference pricing as expressed in the TGP policy.

It is also interesting to note that before the final text of the KORUS-FTA was released, there was some concern regarding its potential impact on US state drug formulary programs (see for example Shaffer 2007). These are used extensively to negotiate drug prices by US state governments, as well as by private insurance companies. Many US agencies such as Department of Defense, and Veterans Administration and Medicaid purchase drugs through cost-effectiveness-based price negotiating programs. Medicaid is run through state governments under federal guidelines providing health insurance.

However, due to the concern expressed by the US public during the negotiations, these US state programs were exempted (for example see Flynn 2007b). For example, ‘government procurement of pharmaceutical products for healthcare’ (referring to the US Department of Defense and Veterans Administration drug procurement programs) appear to be exempt by a footnote under article 5.2. This section also explicitly refers to ‘health care programs operated by its [the Party’s] central level of government’ thereby excluding, and thus protecting Medicaid which is run on the state level. For even greater clarification, article 5.8 contains a definition of ‘health care programs operated by a Party’s central level of government’, which includes a footnote stating that ‘Medicaid is a regional level of government health care program in the United States, not a central level of government program.’

The result is that the provisions do not apply to US government pricing programs, thereby protecting access to affordable medicines within the US,
while continuing to apply to the Korean ‘positive list’ formulary. This highlights even more starkly than AUS-FTA Annex 2C, the clear preferential nature of the medicines provisions in these bilateral trade agreements.

Transparency

Both Annex 2C of the AUS-FTA and Chapter 5 of the KORUS-FTA address the US conception of ‘transparency’ in any healthcare program reimbursing pharmaceuticals. As discussed earlier, the Annex 2C provisions created mechanisms allowing further review of PBAC decisions, calling into question the authority of well established government healthcare institutions.

The KORUS-FTA transparency provisions are similar, but go further than AUS-FTA Annex 2C in providing additional requirements, for example that the parties “within a reasonable, specified period, provide applicants with meaningful, detailed written information regarding the basis for recommendations or determinations.”

Article 5.7 requires the establishment of a ‘Medicines and Medical Devices Committee’ similar to the AUS-FTA MWG. It is likely this committee will play a similar role in helping to shape the US medicine agenda for Korea into conformable domestic legislation.

A major difference in the texts is the requirement that Korea establish an independent review process which appears to allow pharmaceutical companies to challenge decisions regarding pricing or formulary listing (article 5.3 5(e)). While this initially appears similar to the Annex 2C equivalent, a confirmation letter from the Korean government to the US trade representative states that in implementing this section, Korea will establish an independent review body (Kim 2007). This body will be entirely separate to government health care authorities that are involved in price reimbursement schemes and decisions, and will be comprised of ‘professionals with relevant expertise and experience’ with no pecuniary or personal interest in the outcome of the decisions. It is unclear whether this body will have the power to overturn pricing decisions, however it can be assumed that it is unlikely for it to have been established to serve a purely advisory role.

Intellectual property provisions

The KORUS-FTA includes what have been described as ‘TRIPS-Plus’ intellectual property protections, which in general terms work to delay generic competition and allow their royalty life span to be increased for the owners of the multiple patents that now cluster around such products. These include changes to data exclusivity (art 18.9.1), linkage requirements (linking safety approval and patent status) (art 18.9.4), mandatory extensions of patents (art 18.8.6), and patent requirements for new uses of known products (art 18.8.1).
'TRIPS-Plus' is a controversial term which appears to carry an implicit value judgement about the positive value of these changes. An opposing point of view would consider them more deleterious for public health as so (from that perspective) 'TRIPS-minus'.

KORUS-FTA Article 18.9 allows for five years of data exclusivity for new pharmaceutical products and three years for those containing 'a chemical entity that has been previously approved'. This prevents generic manufacturers from accessing the data from clinical trials conducted by the patented equivalent, which would allow them to prove that their product is 'bioequivalent' to the brand name drug. Bypassing the need to repeat stage III and IV clinical trials, generic manufacturers can use data from the original safety and efficacy submission to prove that their drug will behave in the same way. Their early access to the data allows generics to obtain marketing approval, and be ready to market their product as soon as the patent term expires. Data exclusivity provisions prevent generic manufacturers from applying for approval based on the original data during the period of exclusivity, thereby delaying their access to the market. This could become a major hindrance to government compulsory licensing of generic manufacture in a public health emergency. While the TRIPS agreement allows for protection of data from 'unfair commercial use' it has been argued that there are other ways in which this objective can be achieved (Flynn 2007b, p. 4). These provisions once again hinder the Korean government’s ability to further the Korean generic industry. Their existence in the KORUS-FTA text, however, appears to be due solely to aggressive negotiating by the US, rather than lack of a systematic pro-generics negotiating agenda as was the problem for Australia in the AUS-FTA context.

The KORUS-FTA text also contains 'linkage' provisions, which function to prevent safety, quality and efficacy regulatory authorities from giving market approval to generic drugs while the brand name is still under patent. A number of Special 301 Reports issued by the USTR show that the US had a primary goal of forcing Korea to adopt linkage provisions:

The United States encourages Korea to address its lack of an effective coordination system between its health and patent authorities to prevent the issuance of marketing approvals for unauthorized patent-infringing copies of pharmaceutical products. The United States will work with Korea to make progress on these and other IPR issues through the upcoming Free Trade Agreement negotiations (USTR 2006).

Article 18.9.4 provides a similar mechanism to the AUS-FTA equivalent, whereby a patent owner is required to be notified of a generic manufacturer’s request for marketing approval and for the prevention of marketing approval if a patent’s rights are asserted. However, unlike the corresponding AUS-FTA article 17.10.4, the patent holder must first have notified the regulatory authority as covering the particular product. This encourages regulatory oversight of a list of approved pharmaceutical patents, helping to avoid patent
‘evergreening’ and reducing much uncertainty and patent search costs for
generic manufacturers.

Recent US Democrats deal with USTR

In May 2007 a new deal regarding recent US bilateral trade agreements and
their adverse impact on public health was reached between the US Democrats
and the Bush Administration (USTR 2007a). The Democrats negotiated
concessions in a number of areas including patent extensions, linkage
provisions, and to some extent in data exclusivity – thereby eliminating some
of the most egregious ‘TRIPS-plus’ provisions (Committee on Ways and Means
Republicans 2007). This deal was predicted to have an impact on the KORUS-
FTA as well as other forthcoming trade agreements (Weisman 2007). For
example, patent extensions were to be made optional, using terms such as ‘may’
instead of ‘shall’, the Doha Declaration on TRIPS and Public Health and the
so-called ‘Paragraph 6 Solution’ were to be mentioned explicitly (Love 2007).

As it was reached prior to the completion of the KORUS-FTA, this negotiated
agreement with the USTR on public health and trade bilaterals can be used to
interpret the final KORUS-FTA medicines provisions in any dispute settlement
negotiations (Sweeney 2007; Joo 2007). Chapter 16 of the United States – Peru
Trade Promotion Agreement, however, does appear to have taken on these
changes more explicitly (USTR 2007b). Under this revised agreement, the
intention of both parties appears to be that patent extensions for brand drugs
are not mandatory, and generic drugs will become available in Peru no later
than they are made available in the U.S. In addition, patent disputes may be
permitted to be resolved solely through the legal system, rather than through
notification systems in the drug safety approval process. Article 16.3 of this
agreement also allows Peru to take advantage of the so-called ‘paragraph 6’
solution under the Doha Declaration on TRIPS and Public Health which allows
compulsory licences issued by nations with limited manufacturing capacity to
be satisfied by more developed nations. Rwanda recently became the first
country to invoke this TRIPS provision when it announced plans to import a
generic HIV drug from Canada (Anonymous 2007).

If subsequent US bilateral trade agreements do incorporate the concessions
gained through this deal, this must surely also send a signal about how little
national benefit Australia achieved by the passive approach Australian
medicines negotiators took to the AUS-FTA.

A positive Australian medicines agenda for the China and India FTAs

On 18 April 2005, after the completion of a joint FTA Feasibility Study showing
potential for significant economic benefits, Australia and China agreed to begin
negotiations on an FTA (DFAT 2007). While so far pharmaceuticals have not
been considered in the discussions, there are compelling reasons to believe that the inclusion of a chapter on pharmaceuticals in the final FTA will be greatly beneficial to both countries.

As one of the world’s largest manufacturers of generic pharmaceuticals, China has a pharmaceuticals industry predicted to become the world’s 5th largest by 2010, and largest by 2050 (PWC 2004, p. 2). Foreign drug investors see the Chinese drug market as having great scope for growth, with a population of over 1.3 billion, ageing at a projected 3% a year, as well as a very low relative research base, with approximately 97% of manufactured drugs being copies of foreign products or ‘ generics’ (PWC 2004, p. 2–3). Currently, all the top 20 multinational pharmaceutical companies have set up wholly owned subsidiaries or joint-ventures in China (Zhou 2007). While the Chinese market holds huge potential for a large pharmaceutical research and development (R&D) base, the market is currently quite fragmented, partly due to bureaucratic obstacles in centralising the industry, as well as inconsistent intellectual property standards deterring both local and foreign manufacturers (PWC 2004, p. 4). The result is that currently China has only patented two “innovative” drugs (China Economic Information Agency 2002).

Conversely, Australia possesses the regulatory expertise (through the well established mechanisms of the TGA), high quality research institutions, and a strong and growing R&D base (DITR 2007). As well as great potential to enhance the generics industry in Australia, there is much scope to develop the “innovative” pharmaceutical market, leading to large global exports.

As with Australia, but unlike many parts of Europe and the US, China has not only invested heavily in biopharmaceutical sciences, but has also ensured liberal policies towards globally contentious issues such as therapeutic cloning. This is an area which still lacks global consensus, making international collaborative research difficult. As Australia has recently legalised therapeutic cloning by lifting the ban on somatic cell nuclear transfer (SCNT) last year, there is much potential for collaborative research and development in this area through partnerships and joint ventures, which could be greatly facilitated by an FTA.

China is already showing great promise as a potential market for the Australian biotechnology and nanotechnology industries, for example through the patenting in China of BioSilicon™, a nanotech silicon drug delivery system manufactured by the Australian publicly listed company, pSivida Ltd. Furthermore, the CSIRO has been developing and acquiring patents for RNA interference (RNAi) gene silencing technology. Already holding patents in China, representatives from the CSIRO have stated that they see ‘a major market for its RNAi technology in China’ (O’Neil 2005).

The rise of an Indian multinational pharmaceutical industry with strong intellectual property protection and interest in rapid marketing of safe biologic generics, is a phenomenon that can hardly be disregarded by Australian negotiators to any trade agreement with that nation. India’s pharmaceutical industry now ranks fourth in the world and its firms produce 20% of the
world’s APIs. (Lofgren 2007) Interestingly from Australia’s point of view, Indian firms meet 70% of that nation’s pharmaceutical demands. (Lofgren 2007) The international competitiveness of top-tier Indian medicines firms now attracts the best national graduates and Indian firms have begun to make significant foreign acquisitions. (Lofgren 2007) Both India and China, also with high relevance to Australian interests, are actively investing in a ‘modular’ model of decentralised biotech R&D involving global distribution and semi-autonomous activity (Goodall et al, 2006).

It has previously been suggested that in establishing a pharmaceuticals chapter within a CHINA-AUS-FTA, a Medicines Working Committee could be set up to facilitate dialogue about cooperative research, manufacture and distribution of pharmaceuticals (Faunce 2005). The value of such a committee would be even more apparent in an INDIA-AUS-FTA. The parties through such a committee could facilitate ongoing discussions at the highest policy levels about establishing, for example, regulatory mechanisms similar to Australia’s PBS, sharing expertise, data, assessments and methods of comparing effectiveness and objective therapeutic significance of existing and new medicines. The tradition of public health focus in government policy could make this an attractive proposition for Australia, India and China. The operation of the similar MWG under the AUS-FTA provides a precedent. It will be quite a peculiar circumstance from the Australian point of view if the AUS-FTA contains such a medicines committee. Intellectual property provisions reflecting the new pro-global public health position negotiated in the US, also could be included in the medicines provisions of the trade agreements between Australia and India and China respectively.

There are thus a variety of significant factors suggesting the value of Australia now taking a more active role in using these trade deals to negotiate for positive national and transnational benefit in health technology areas where it maintains a competitive advantage (such as bio and nanobiotechnology basic research).

Conclusion

The Australian and Korean trade agreements with the US were the first to include pharmaceuticals chapters. During negotiations for both, the US pursued a strong agenda to change certain aspects of the domestic health policies of each country, particularly by getting rid of reference pricing mechanisms in the Australian PBS and limiting their capacity for introduction in the Korean positive list formulary. Recent legislative changes to Australia’s price referencing mechanisms show that despite assurances from Australian negotiators, some core aspects of the PBS, and in turn Australian health policy, were in fact negatively affected by the AUS-FTA. Whether or not a similar adverse impact on domestic health policy is observed in Korea remains to be seen.
Unless changes in Australian policy towards enhancing national and transnational benefit through health technology provisions in trade agreements are made soon, then regardless of the bipartisan deal negotiated by the US democrats, the AUS-FTA and KORUS-FTA may provide the unfortunate model for future medicines provisions in FTAs entered into by Australia. The new Australian government, with its apparent agenda of transparency in government, may see the value in a clear articulation of a domestic trade agenda in legislation (such as that of the US), which ensures that particular national and transnational goals in health technology policy are developed, maintained and promoted during trade negotiations. This could include, for example, the establishment of similar advisory bodies to the US IFAC committees and the AUS-FTA MWG, which could monitor and report on the protection of Australian interests both during and after trade negotiations such as those with China and India.

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