

TRIPs FORUM: A Matter of Interpretation

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South Bank College of Art Campus, Griffith University

Christopher Arup, Professor, Law School, Victoria University, Melbourne

Introduction

This paper makes a small contribution to our understanding of the interpretation of the TRIPs agreement. It is also to serve as a report on my own previous work.

The paper offers a way of thinking about the field and some snapshots of interpretations over time – not just the record of interpretive practices but the continuing competitive efforts to structure interpretation selectively and steer a path through the criss-cross of regulation. Of course interpretation is not a mechanical task, it depends on who is deciding and the styles and sources of law for deciding.

To understand contemporary law making across the world, I have found that socio-legal studies has much to offer. Many in socio-legal studies would now recommend that we do not start by looking for formal hierarchies of legal authority and settled, static rules of conduct. Globalisation blurs the boundaries between jurisdictions of law and multiplies the encounters between divergent legalities. Better now to track the currents, circuits and communities of interpretation. Organising principles like regulatory networks, global governance and legal pluralism will provide greater assistance.

As a force for convergence of law, the impact of TRIPs should not be underestimated. It provides a strong pro-rights framework for any consideration of intellectual property policy. TRIPs is by no means the first international convention, but we could say it has truly placed intellectual property rights on a global scale. It is remarkable that we can all be involved in the 'same' conversation about intellectual property. Given the range of the WTO membership and the substance of its prescriptions, almost every measure can now be read as a response to TRIPs.

Legal Pluralism

Yet as socio-legal scholars we remain alert to diversity in the living law – in this instance the sheer variety of private and public intellectual property law around the world. Even an institutionalisation at the international level such as the WTO gives

politics and culture another space in which to play, as much as it produces legal rules to be applied. If TRIPs is the key reference point, broadly the potential lies in what Peter Drahos characterises as a shift from coercion to dialogue.¹

In part this potential is due to the nature of the agreement itself. In the early days of the WTO, the common contention was that law would replace political power based relations and deals made within closed circles with a transparent rule based multilateral regime.² The WTO would give security and predictability to the conduct of trade relations and within this rubric intellectual property protection. In the most expansive view, the WTO agreements would become the constitution for a world economy. Legal constitutions constrain while authorising the operation of politics. So WTO law would be at the harder end of the spectrum of law. The agreements would produce rules and the task for the dispute settlement system would be to apply those rules, adjudicating on complaints of non-compliance.

Some ten years on, the evidence points to a familiar finding for socio-legal studies. WTO law does not operate in an autonomous space but interacts with the economic, political and cultural currents that run through the WTO. The provisions of the agreements form part of the framework for the conduct of trade. The legal processes have an impact on the calculations of the parties, they encourage cooperation and compliance, and they stimulate further discourse over norms. Nevertheless, we find that legal practices are influenced not just by internal considerations such as rule-conformity but by economic rationalities, political sensitivities and cultural mores.

Implementation has revealed the play in the system and recent experience is marked by the emergence of fault lines within the developed countries, the increasing assertiveness of some of the developing nations, and the articulation of alternative views of intellectual property resources and entitlements. This contingency provides an opportunity to argue for competing interpretations of WTO texts like TRIPs.³

My own work has argued that, even if TRIPs was the most emphatic of the WTO agreements, its gaps, generalities, ambiguities, allowances, irresolutions and postponements would necessitate mediation between the different legalities.⁴ While

¹ Drahos (2002).

² Eg. Young (1995).

³ Eg. Lawson (2004).

⁴ Starting with The New World Trade Organization Agreements (2000).

there is a natural interest in any move to legalisation, this looser fit finds resonance in much contemporary international relations and international law scholarship too.⁵ It employs a more relaxed sense of where law is to be found as well as what it is. It lets in law making not just by nation states and international conventions, but also by aid banks, philanthropic foundations, multinational corporations, indigenous peoples, research groups and share networks.⁶

So, TRIPs and the WTO might strive to be self-contained but the many soft spots mean that other texts and processes enjoy scope and sphere of operation too. Those other legal sources could be local custom, informal understandings, marketplace transactions, national constitutions and legislation, state and municipal government laws, administrative and judicial rulings, bilateral and regional agreements between governments, transnational epistemic, advocacy and regulatory networks and official international organisations and treaties.⁷

In this criss-cross of the field, the challenge to all scholars is not just to identify multiple sources of intellectual property law but to map the interactions between them. Boaventura de Sousa Santos calls this 'inter-legality'.⁸ The interest lies in locating the actors, principles and processes that mediate the interaction between them.⁹ In this regard, I recommend the concept of the interface; interpretation then is part of the interface between legalities.

The Field of Interpretation

Interpretation reaches out beyond the text of a treaty. The axes run both vertically and horizontally. We expect international law to limit the nation state's choice of intellectual property regulation. International standardisation or harmonisation can be understood as an effort to overcome the uncertainty of conflict of laws and regulatory competition. But such law does not simply constrain national law. It might coordinate national regulation, so countries can be confident that other, possibly more powerful, countries will need to abide by the same standards. Then it might consciously leave gaps for national legislation and lower levels of law to operate, while setting minimums on which they can advance unilaterally or bilaterally. Or it

⁵ Finnemore and Toope (2001).

⁶ Jenson and de Sousa Santos (2000).

⁷ Shaffer (2003).

⁸ de Sousa Santos (2002).

⁹ Braithwaite and Drahos (2000).

may direct while expressly allowing countries to take exceptions or attach qualifications.

Horizontally, international and transnational law are not simply in competition for supremacy. They find spaces in which to defer to each other's view or draw on each other's resources. Compliance might be shown, for example, by adherence to the standards of another international convention or to customary law. An interpretation might be sought, at least, that reconciles an agreement with other international law.

Interaction occurs not just when new treaties are being aligned against existing treaties, domestic law and other sources of law. It is often an ongoing process. Interaction is built into the implementation of a treaty. We see this now in the implementation of TRIPs: the opportunity to exercise restraint in questioning compliance, the provision of alternative paths to compliance, negotiation, compromise and settlement of disputes, and the opportunity for the members to come together to declare authoritative interpretations or grant waivers of obligations.¹⁰

Given the weight of the WTO, much of the mediation occurs within and around the WTO itself. The agreements form part of the framework now for interpretation. But it also occurs out on the broad terrain of international intellectual property. While the legal processes of the WTO present opportunities to channel the issues, the members are also prepared to go outside the WTO to resolve issues. Eventually those external solutions may play back on the WTO.

Despite these efforts to impose order, much of intellectual property policy is only loosely connected to the international field. Private practices shape a trans-national field like this too. The practices vary. When thinking of patents, for example, the practices might range from the commitment made by a group of scientists to publish their human genome findings on the web, the licensing and litigation strategies of the major rights holders, for example in relation to essential drugs, the pattern of copying and free sharing by secondary producers and end users, and the decisions of companies such as Celera to rely more on other assets such as informatics services to extract value from biotechnology.

¹⁰ Arup (2004).

We can see the variety in the challenge to copyright too from open systems software and music file sharing. This produces a response. With home country support, the producers litigate across national boundaries. When that litigation meets difficulties in particular jurisdictions, they seek to reshape the framework of international law to bring it under control. If the multilateral agreements are too vague or too intractable, a bilateral initiative might be the way to build a more specific and secure prescription.

As lawyers we remain interested in how clashes are resolved for the time being and rulings obtained in a particular case.¹¹ Neither is this dogged inquiry out of keeping with the inquiries made in other disciplines. They may still stress the part that power plays (persuasive, coercive, hegemonic) in determining relationships between sources of law. For instance, we would expect certain public-private coalitions to seek to have their models adopted as the international norm. Some such models are exported directly to other countries; others are inserted into the workings of the international networks and institutions.

The formative context will continue to shift. Coercion may take the place of dialogue again. Ideas rise and fall; the prominence of particular countries and movements too. Recently, for example, I was struck by a report linking trade mark counterfeiting with Islamic terrorism.¹²

Some see signs of a new jurisprudence, at its strongest a new constitutionalism, that would entrench transnational rights of commerce and property over national public regulation. The new constitutionalism has both a substantive program and a legal approach.¹³ In substance, global producers, traders and investors will enjoy commercial freedoms and property protections worldwide. Legally, there will be careful specifications, not just of the content of those rights, but also the means by which their interpretation will be determined. The specifications include the constitution of the tribunals which rule on disputes and the sources on which they draw.

At this stage it is doubtful whether constitutionalism is a helpful way to characterise the WTO and the TRIPs agreement.¹⁴ However, it is fair to say the cross-currents

¹¹ Eg. Pauwelyn (2003).

¹² The Age, 20 November 2004).

¹³ Schneiderman (2000).

¹⁴ Von Borgandy (2003). See now Joerges, Sand and Teubner (2004). Cf. Cass (2001).

and counter views have really only managed to keep the agreement open in certain respects. They have not resulted in any rewriting of the rules, whether to make intellectual property work for independent and alternative producers or to guarantee access for essential uses outside the forces of the market. If the current round of negotiations comes to nothing, we may see a return to the dispute settlement system and competition between the legalities.¹⁵

Furthermore, the pressure to secure and extend intellectual property rights is being applied at other points. Most notable is the bilateral FTAs, which promote detailed substantive requirements and seek to control relationships with other sources. Those wishing to limit the space outside the framework of property rights do not let up; they shift their interpretative strategies to another tack. This pressure will have a cumulative effect, modifying the impact of TRIPs itself.

WTO Dispute Settlement

The story of the making of TRIPs is well told. That story remains important to explaining how the agreement is structured. TRIPs does not confine itself to non-discrimination, so that countries may at least continue to determine the level of protection suitable to their economic cultural and social needs at any one time. We know that TRIPs embodies the major categories of property, with accompanying rights backed by provisions for enforcement.¹⁶

For many countries, at least in categories like patents, TRIPs meant major extensions to their national legislation and for some, more profoundly, reform of their administrative systems and judicial bodies. Even for developed countries like Australia, there were to be noticeable adjustments, the term of protection for patents for example extended from seventeen to twenty years.

The idea of a trade related intellectual property agreement began with the concern over counterfeit and pirated goods crossing national borders. With a big push from the United States, and the intellectual property industry alliances urging it on, it grew to represent the idea that lack of adequate and effective protection behind the border was a restriction on trade. Drafting the provisions saw members of the EU, Japan and others of the developed nations come on board. Some developing countries expressed opposition to a TRIPs agreement but most were placated.

¹⁵ McRae (2004).

TRIPs can be characterised as the trade-off for access to other benefits in a world economy, for instance markets for agricultural produce and direct foreign investment. But it has also been suggested, whether for lack of information or because of the reassurances of others, many countries were not fully aware of the implications of the agreement at the time.¹⁷ When connected to the apparatus of the WTO, the substance of TRIPs means all the members are caught squarely in a dialogue over interpretation. Sometimes, they have a fight on their hands. Rather than revisiting the text of the agreement here, I shall say a little about the experience with dispute settlement and the other ways the WTO has sought to guide the meaning of TRIPs.¹⁸

WTO dispute settlement starts with the notification of a complaint by a member country and the conduct of consultations to see if a mutually acceptable solution can be achieved. As in domestic civil justice, WTO complaints are often settled 'out of court'. After ten years, the TRIPs agreement has attracted few rulings of substance. Complaints set up a bargaining relationship. The freedom to settle may produce creative solutions that go beyond mere observance of the legalities of the agreement.

While article 3.5 of the DSU says all solutions formally raised under the consultation and dispute settlement provisions shall be consistent with the covered agreements, the notifications do not appear to be screened rigorously by the DSB for their legality. It is for the parties to determine whether a change to domestic legislation is necessary to bring it into conformity with TRIPs. The force of the complaint might be sufficient, at least for those who are not comfortable with protracted litigation.¹⁹

Only now is a jurisprudence emerging that might place a legal check on the bringing of complaints, the request for consultations and the establishment of panels. So too a panel ruling that a provision is non-conforming does not necessarily produce compliance. As well as recourse to the Appellate Body, there are opportunities, which again may favour the more powerful countries, to go to arbitration over what constitutes compliance with a ruling. Many developing countries are daunted by this kind of procedural exhaustion, especially when their markets are not big enough to

¹⁶ Eg. Blakeney (1996); Gervais (2003).

¹⁷ Drahos and Braithwaite (2002)

¹⁸ Based on Arup (2003, 2004).

¹⁹ Shaffer (2003).

make retaliation a real threat in the first place. So, it seems interpretations can be resisted as well as promoted.²⁰

Listening

Reviewing dispute settlement, I nominated five aspects of decision making that shape the interpretations the panels make. In dispute settlement, and producing a TRIPs jurisprudence, the panels might choose between open and closed, literal and purposive, insistent and deferential, narrow and broad approaches to interpretation. Within guidance from the WTO Agreement and the Dispute Settlement Understanding, choices are made about receiving messages, finding meaning, managing clashes with national and international law, and reaching limits.

If I can highlight one aspect of interpretation here, it is the extent to which the panels let in consideration of sources external to the words of the substantive requirement itself. In the WTO context, to place greater weight on external sources is to allow discussion of the politics of meanings.

One way to do so is to embrace external views, not just the views of the complainant and respondent government parties, but third party governments and non-government organisations. The amicus curiae issue has itself involved the interpretation of the DSU article affording the tribunal the right to seek information and technical advice from any individual or body it considers appropriate.

A second is to read the text holistically, giving genuine weight to the preambles and statements of objectives and principles that might capture the important political compromises of the agreement.²¹ The DSU says the provisions of the agreements may be clarified in accordance with the customary rules of interpretation of public international law. The Appellate Body has accepted that those customary rules include the Vienna Convention on the Law of Treaties. The Convention in turn provides that a treaty should 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.²²

²⁰ Ghanotakis (2004).

²¹ Shanker (2002).

²² Lennard (2002).

This search for context might also draw in the other WTO agreements, not just in their direct application to trade in goods and services with intellectual property content but for the sake of interpreting TRIPs itself. One example is the link between agriculture and geographical indications.²³

Of course a key question is the scope to be allowed to national measures before they are ruled non-conforming with TRIPs. Faced with a complaint of inconsistency, a panel is required to interpret both the WTO provision and the national measure in question. It is offered the respondent's own characterisation of the national measure as being consistent with TRIPs, or perhaps an assurance that it will administer the measure in a manner that is consistent (see also article 1.1).

To what extent should the panel defer to that characterisation? Should it, as part of its standard of review, give the national measure a margin of appreciation?²⁴ Instead, the allowance for the national measure, and the means for managing difference, may be found in the liberal way the TRIPs provision itself is interpreted. Interestingly, Picciotto asks whether this allowance should be made for stronger as well as lighter protection at the national level.²⁵

The panels must also manage the relationship with other international treaties and the general (non-convention) international law. Here the tribunal faces a choice whether to insist on the precedence of the TRIPs agreement to the exclusion of other international law, or to find a way to accommodate and thus to promote the standards being set in other international forums.

Only rarely do the WTO agreements make such links expressly. An exceptional case is the incorporation of selected Paris and Berne articles within TRIPs. Otherwise, the argument largely is whether that law forms part of the surrounding rules of international law, which may, on the strength of Vienna article 31(3)©, be taken into account, at least in interpreting the provisions of the TRIPs agreement itself.²⁶ Such an openness is vital to the tenor of TRIPs. It contemplates not just the other IP

²³ Blakeney (2001); Van Caenegem (2003). The panels have already encountered some problems applying GATT jurisprudence to such a distinctive agreement as TRIPs.

²⁴ Howse (2000).

²⁵ Picciotto (2002).

²⁶ Bartels (2001).

conventions such as the WIPO treaties,²⁷ but international treaties with an alternative take (somewhat) on the field such as the United Nations Convention on Biological Diversity.

Likewise, in reaching limits, the panels must decide how ready they are, not just to resolve ambiguities, but to fill gaps in the agreements where they fail to offer a solution to the dispute. Should they feel free to build a common law of international trade? Some take the view that the gaps and limits are there deliberately; they represent the decisions taken at the negotiation stage over the legitimate reach of TRIPs.²⁸ In support, DSU article 3.2 says that the rulings of the panels cannot add to or diminish the rights and obligations provided in the covered agreements.

Some are now advocating recourse to equitable principles to temper the application of the TRIPs agreement. Such WTO rights should be exercised fairly and in good faith, out of consideration for the developing countries, which have in the past enjoyed allowances of special and differential treatment (see also the DSU article).²⁹ However, a willingness to fill gaps could result in stronger protection. Also pending is the availability of non-violation complaints, which would increase the scope for protective interpretations again.

Rulings in Canada-patent protection for pharmaceutical products³⁰ and United States-homestyle exemption³¹ exemplify the many interpretive choices for the panels. They include preference for literal or purposive approaches, the resort to dictionary definitions, the status of the preambles and objects clauses, the relevance of the negotiating histories of the agreements, the relationship to other treaties as well as the special position of the incorporated conventions and their *acquis*, the reading of the national measures, the application of GATT jurisprudence, the scope afforded by the customary rules of interpretation of public international law, and the role for the principles of international law generally.

²⁷ In US-homestyle exemption, the panel was happy to try to reconcile TRIPs with the WCT and WPPT because they were 'part of the same corpus of international intellectual property protection'.

²⁸ Krajewski (2001).

²⁹ Footer (2001).

³⁰ Canada-Patent Protection for Pharmaceutical Products, WT/DS114/R, 17 March 2000.

³¹ United States-s.110(5) of the US Copyright Act, WT/DS160/R, 15 June 2000.

Shifting Forum

They also hint at the wider strategies to manage interpretation. It is notable neither ruling was taken to the Appellate Body. Yet, overall, most panel reports are appealed.³² The Appellate Body is charged under DSU article 17.6 to examine the issues of law covered in the panel reports and the legal interpretations developed there by the panels. It has largely seen its role as encouraging legality and it has been critical of the legal errors and excesses of the panels.³³ But the Appellate Body has engaged in judicial activism too. The Body has reversed the panels' rulings, in full or in part, in the majority of these appeals.

Post Seattle, we see that the management strategies search wider again, with the members withholding key issues from the disposition of the tribunals. At a delicate moment for relations between the North and the South, the multi-claim disputes, United States-Brazil and United States-Argentina, were settled out of court.³⁴ Then at the Doha Meeting of Ministers, the members fashioned a collective solution to interpretation on the issue of TRIPs and public health. The Doha Declaration is designed to shield from legal challenge the use individual members make of relevant TRIPs allowances.

Under the authority of article IX.2 of the WTO Agreement, the members adopted an authoritative interpretation liberal in its interpretation of TRIPs articles 31 and 6. Among its provisions, it states that each member has the right to grant compulsory licences and the freedom to determine the grounds on which such licences are granted; each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDs, tuberculosis, malaria and other epidemics, can be so; and each member is free to establish without challenge its own regime for the exhaustion of rights.³⁵

After the Declaration, issues remained to be resolved within the proceedings of the TRIPs Council. Article 31(f) is read as insisting that compulsory licensing should be predominantly for the supply of the domestic market of the member authorising such use. Some needy countries do not have the local manufacturing capacity. It took

³² Leitner and Lester (2004).

³³ Weiler (2001); Ehlermann (2002).

³⁴ Czub (2001).

³⁵ WT/MIN901)DEC/2, November 20, 2001.

almost two years for the WTO to construct an administrative system that permits trade in generic drugs under compulsory licence.³⁶

On this occasion the members prefer the option of a waiver of the condition in article 31(f) over an authoritative interpretation of article 30 to allow the leeway. Perhaps a permissive interpretation this time would have been too blatant an abuse of the legalities.³⁷ But the waiver is a temporary one, meant to last only until article 31(f) is amended. The in-built agenda items indicate how difficult any amendment of TRIPs is proving. Members are wary of opening the agreement to review.

The system is elaborately constructed requiring detailed supervisions by both exporting and importing countries. Paradoxically, it may generate demand for interpretation itself. Knowingly, Braithwaite and Drahos observe that the provisions reveal a familiar pattern: 'Developing countries are drawn into complex juridical webs that they do not have the resources to disentangle and that ultimately do not serve them'.³⁸

Those wanting the allowances to be contained do not let up; with their considerable resources, they pursue their interpretive strategies elsewhere. In the TRIPs Council, the United States Government has argued with others over how to read the concession in the Declaration of 'public health crises including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics'. The prospect of dispute over the application of the system may be relieved somewhat by the undertaking of 23 developed countries not to use the system to import generic drugs into their own countries. But five others (Hong Kong, China, Mexico, Singapore and Turkey) have announced they will only do so in 'public health emergencies'.³⁹

Other issues have been kept from TRIPs interpretation by pursuing dialogue in a forum outside the WTO. For example, members might have used dispute settlement to test the TRIPs legality of systems for the recognition and reward of traditional knowledge. These systems might be TRIPs-consistent either as a condition placed on patentability of plants and animals or as part of an effective sui generis system for the protection of plant varieties.

³⁶ WTO News Press/350, August 30, 2003. Further see Matthews (2004) and Rafiqul Islam (2004).

³⁷ But see Shanker (2004).

³⁸ Braithwaite and Drahos (2004: 220).

³⁹ Kirby (2003).

Members are holding back from disputation partly because the plants and animals exception is under review. Some countries want TRIPs amended to make such a system a requirement, rather than a permissible space in which countries try to obtain acceptance of their own system individually. The trade-off will be agreement to patent protection for plant and animals becoming obligatory. The question is whether it would be better to leave traditional knowledge to WIPO or the CBD.⁴⁰ Ultimately a reconciliation with TRIPs may be a necessity.

The Bilateral Free Trade Agreements

The new wave of FTAs is not just another source of intellectual property law within the regulatory criss-cross that patterns the field. The FTAs bear on the interpretation of TRIPs. They bear a complex relation to TRIPs, one that is partly supportive, partly supplementary, and partly competitive too.

The US and the EU have been active promoting intellectual property provisions bilaterally. Their initiatives take different forms. For the developing countries, a BIPs may come as a condition for obtaining a BITs with a source of much needed capital. These countries are softened up too with the threat of trade sanctions, withdrawal of aid and preferences, and complaints to the WTO.⁴¹ The FTAs can offer the prospect of improved market access for industrial goods and agricultural produce, proving attractive to developed countries such as Australia too.

FTAs-TRIPs

Securing commitments from the bilateral partner is part of a broad strategy to strengthen intellectual property rights. While TRIPs is substantial, the bilateral demands are 'TRIPs-plus' in several ways. They rewrite some of the TRIPs obligations for the sake of greater certainty; they seek further protections (both higher and wider); they ask the partners to forego allowances given them under the consensus decision making of the WTO; and they urge the partners to sign up to international treaties that are breaking new ground.⁴²

Each FTA gain in intellectual property rights is expressed as a minimum and the partners remain free to extend protection further again. Interaction with the TRIPs

⁴⁰ Dutfield (2001); Sherman (2003).

⁴¹ Drahos (2001); Price (2004).

⁴² Sell (2003).

agreement means the minimums are adopted on an MFN basis, so they are spread immediately to other members of the WTO too. Thus the partner serves temporarily as the pace setter for intellectual property internationally. A 'script' is written for subsequent bilateral agreements and possible consolidation in a new round of multilateral treaty making. The script is carefully revised and refined in the light of the experience of the previous agreements, both bilateral and multilateral.⁴³ So the results will be felt back at the WTO, though resistance here to further advances is a reason why much of the focus currently is on the proliferation of FTAs.

This drive to cut through the troublesome vagaries and allowances of TRIPs can be seen close at hand in the Australia-United States Free Trade Agreement.⁴⁴ While Australia would not seem a big intellectual property concern to the United States, the FTA is an opportunity to trial United States prescriptions with a developed nation outside the region.

In his statement of objectives for the agreement, the US Trade Representative writes of establishing standards that build on the foundations established in TRIPs and other agreements such as the WIPO Treaties; seeking to enhance the level of protection beyond TRIPs in new areas of technology, such as internet service provider liability; in other areas, such as patent protection and protection of undisclosed test data, seeking to have Australia apply levels of protection and practices more in line with US law and practices; and seeking to strengthen Australia's domestic enforcement procedures, including criminal penalties, to deal with piracy and counterfeiting.⁴⁵

Pharmaceutical Patents

This approach is evident on several fronts. A good example is the specifications for internet service provider liability. Here I shall pursue the example of patents. The backdrop to this intervention is the continuing campaign to ensure that the rights of pharmaceutical producers are safeguarded when there is concern over access to essential medicines. The United States wants to ensure that cheaper generic drugs or discounted brand-name lines are not re-routed from the developing countries to the more affluent markets like Australia. It wants also to discourage developed

⁴³ Arup (2004a).

⁴⁴ Arup (2004b).

⁴⁵ USTR Letter to Congress on US Objectives, November 13, 2002, at www.ustr.gov/releases/2002/11/2202-11-13-australia-byrd.

countries from becoming involved in the manufacture of generics, under compulsory licence, either for their domestic market or for export.⁴⁶

Within AUSFTA, the intellectual property rights chapter begins by making reference to key multilateral agreements. Each party affirms it has ratified or acceded to a list of such agreements. The list includes the Patent Cooperation Treaty (1970), the Paris Convention (1967) and TRIPs (1974). Each party promises to make its best efforts to comply with the provisions of the Patent Law Treaty (2000).

However, AUSFTA makes express provision for patent rights too. In certain instances, its specifications restate as well as add to the provisions of TRIPs. In a truncated version of TRIPs article 21.1, AUSFTA article 17.9 opens by requiring each party to make patents available for any invention, whether a product or process, in all fields of technology. TRIPs article 27.1 meant that many developing countries would have to give patent protection to pharmaceutical products for the first time and the US FTAs have sought to speed up that process.

AUSFTA goes on to say that the parties confirm that patents shall be available for any new uses or methods of using a known product. This kind of 'refinement' is significant even in the established jurisdictions like Australia when pharmaceuticals are candidates for patents. It is relevant to the emerging 'evergreening' issue.

Like TRIPs, the requirement to offer patents to inventions is subject to the proviso that each application meets the technical criteria, novelty, inventive step and industrial application. AUSFTA also intervenes in domestic administration by formalising the USPTO policy. It requires each party also to provide that the claimed invention is useful if it has a specific, substantial and credible utility. This policy has previously been spread at the level of contacts between the national patent offices as part of the Trilateral Cooperation Commission.⁴⁷

AUSFTA confines the permitted exclusions to patentability to two of the TRIPs categories, the ordre public and morality exception and the methods of treatment exception. A source of the dialogue at the WTO, the exception for plants and animals, is simply eliminated.

⁴⁶ Kuhlik (2004). Also the 'leakage' of pharmaceuticals provided at affordable prices under public pharmaceutical benefits schemes, see Drahos, Lokuge, Faunce, Goddard and Henry (2004).

⁴⁷ Davies (2002).

We saw that those interpreting TRIPs have faced difficulty reconciling the article laying out the patent rights with those making allowances for exceptions to infringement. Here especially, AUSFTA aims to cut through the uncertainties of TRIPs; it is purposeful circumscribing Australia's options.

AUSFTA does not repeat the TRIPs article 27.1 requirement for patents to be available and patent rights to be enjoyable without discrimination as to place of invention, field of technology, or whether products are imported or locally produced. Neither does it include the TRIPs article 28 enumeration of the patent's exclusive rights, which are to prevent third parties from making, using, offering for sale, selling - or importing for those purposes.

Following the language of TRIPs article 30, AUSFTA allows the parties to provide limited exceptions to patent infringement. Like TRIPs article 31, it allows for the government parties to grant compulsory licences in the case of national emergency or other circumstances of extreme urgency. But here it varies the conditions for those licences.

With that set-up, it then ties down key rights. Two instances shall be cited here before we move back to dispute settlement. AUSFTA does not adopt TRIPs article 6. The United States has argued that the article is not substantive.⁴⁸ It just keeps issues of exhaustion, and the legality of importing copies for sale in a market overseas, out of WTO dispute settlement. Other countries say it means, despite articles 27 and 28, that a member country may authorise parallel importation. The AUSFTA article aims to secure the patent holder's rights to control imports. It requires each party to provide that the exclusive right of the patent holder to prevent importation shall not be limited by the sale or distribution outside its territory, at least where the patentee has placed restrictions on import by contract or other means.

Article 17.9.6 plays off TRIPs article 30 and the panel ruling in Canada-Pharmaceutical Patent Protection.⁴⁹ It controls the use of the subject matter of a subsisting patent. If, under the limited exceptions allowed to the exclusive rights, a party permits the use of the subject matter to generate the information necessary to

⁴⁸ Abbott (2002).

⁴⁹ Canada-Patent Protection for Pharmaceutical Products, WT/DS114/R, 17 March 2000. See Shanker (2004).

support an application for marketing approval of another pharmaceutical product, that product must not be made, used, sold, or *exported* for any other purpose.

It may be one reason for restating certain of the TRIPs (and other) multilateral provisions is to give the parties access to the inter-governmental dispute settlement process of the FTA - where AUSFTA overlaps with TRIPs, not just where the FTA carries TRIPs-plus rights. In any case, the coverage of the two might be hard to separate. Where non-compliance with a WTO agreement is alleged, the WTO DSU presses members to use the WTO itself for redress.⁵⁰ However, in article 21.4, AUSFTA purports to give the complaining party a choice between its own dispute settlement and the WTO.

That choice will involve consideration of several factors. One will be the constitution of the panels.⁵¹ What will be the reference points for AUSFTA interpretation? The dispute settlement chapter of AUSFTA states that the panels shall 'consider the provisions of the Agreement in accordance with applicable rules of interpretation as reflected in Articles 31 and 32 of the Vienna Convention on the Law of Treaties'. If the complainant chooses the FTA process, will the application of Vienna Convention articles 31 and 32 let in consideration of the WTO TRIPs jurisprudence or that of the other multilateral conventions? Nothing of the Doha Declaration is included in AUSFTA.

Already we can see this shopping for interpretation at work. The United States Administration has been unhappy with the Australian Labor Party's response to AUSFTA article 17.10.5. The article is one of a set restricting the use that secondary producers, the producers of generic drugs, may make of undisclosed test data that the patent holder has submitted as a condition of obtaining marketing approval for a new pharmaceutical product.

Article 17.10.5 requires the parties to provide measures to prevent the secondary producer from marketing a product or a product for an approved use, where that product or use is 'claimed in a patent'. To implement this requirement, the Government places an obligation upon the secondary producer, when it seeks marketing approval, to certify that it will not be doing so. This places the onus on the

⁵⁰ DSU Article 23, see US-ss.301-330 of the Trade Act of 1974, WT/DS152/R. 22 December 1999.

⁵¹ John (2004). Note the US does not have a perfect record of compliance under similar procedures elsewhere such as NAFTA, see Arnett (2003).

secondary producer to challenge the scope of subsisting patents and creates a further incentive to 'evergreen' patents for popular drugs.

As we know, the Labor Opposition has countered with an amendment requiring the patent holders to certify the bona fides of any infringement proceedings they might take against the secondary producer who does go to market. They must certify that the proceedings are commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay. A court may apply a penalty if the certificate is false. The amendment also provides for orders if the plaintiff obtains an interlocutory injunction in such circumstances.

The US Administration first expressed its concern by reserving its rights to certify that Australia's implementing legislation was in accordance with the AUSFTA requirements.⁵² It suggested that the Opposition's amendment undermines the FTA's protection for patents. But it has raised a further point: that the amendment runs contrary to the TRIPs requirement, omitted from the AUSFTA counterpart, that patents be granted and rights enjoyed without discrimination as to field of technology.⁵³ In November 2004, the US certified compliance after obtaining an undertaking from the Australian Government that it would not use the amendment against US producers. At the same time, the US signaled it was prepared to take its complaint to the WTO against the measure if the undertaking was not honoured.⁵⁴

⁵² Australian Financial Review, 13-14 August and 20-21 August 2004.

⁵³ Note Canada's complaint against the EC, WT/DS153, 2 December 1998, not prosecuted.

⁵⁴ Australian Financial Review, 23 November 2004.

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