Negotiating IP in FTAs: Preserving & Enhancing Flexibilities

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Outline of Presentation

- Introduction
- Background on SACU
- Possible problematic TRIPS-plus measures
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- Concerns in copyright
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Background to SACU (1)

- SACU formed in 1910 to establish free trade of goods and to impose a CET on imports from non-SACU member countries
- Revenue from external tariff is shared
- SACU Members consist of Botswana, Lesotho, Namibia, South Africa and Swaziland.
- Strong dominance of SA results in polarization
- SA accounts for 91% of regional output, 87% of population
- SA's use of unilateral tariff protection against foreign trade diverts trade to SA, creating trade for itself within SACU and causing an anti-export bias in the region
- Under 1969 Agreement all discretionary and policy making powers vested in RSA
- Limited scope for consultation between member states
- Compensation to BLNS necessary through revenue sharing
- No formal institutional structures except for the SACU Commission – official met randomly
- Officials attend randomly commission meetings
- New SACU Agreement of 2002 reflects changed mandate.

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Background to SACU (2)

- Move away from excessive focus on revenue sharing.
- Objectives include facilitating the development of common SACU policies:
  - (Balanced) Industrial Development Policy
  - Agricultural Policy
  - Competition policy
  - Unfair trade practices
  - More democratic decision-making
  - Establish new institutions (e.g. SACU Secretariat, Tariff Board, Tribunal etc)
  - Revised revenue sharing formula (excise, customs & development components) → negative impact of liberalization

Background to SACU (3)

SACU faces a number of challenges

- Existing provisions of new SACU Agreement are problematic
- Not a true 'customs' union beyond goods → need to address services, no common policies, harmonization
- Development challenges, diversification, preference erosion etc
- Highest prevalence of HIV/AIDS, low incomes to purchase essential medication
- South Africa the only Member with significant manufacturing capacity → its response to treatment affects other SACU Members
- Currently some drugs are available from generic suppliers while others only under patent
- Availability of some generics was due to civil society action in a 'competition' complaint against GlaxoSmithKline and Boehringer Ingelheim
- Despite some improvements, SA prices for ARVs are still higher than best world prices. There is scope for further price reductions, for example, through pooled regional procurement, recourse (real/threatened) to public health safeguards and regulatory flexibilities in the TRIPS
- Little attention so far on the cost of medicines for prevention and treatment of opportunistic infections which remain excessively high

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The SACU/US FTA

- FTA talks notified end of 2002 → aim to lock in AGOA benefits, stimulate investment, enable greater US contribution to development
- New SACU Agreement requires negotiating as a bloc (e.g. EFTA)
- US objectives (USTR):
  - Address tariff and non-tariff barriers to US exports
  - Inadequate protection of intellectual property rights
  - Address SACU restrictions to US services suppliers
  - Advance US for the WTO negotiations → go WTO and US-plus
- Is the scope of the FTA too broad for SACU?
- Does the outcome envisaged by the US support SACU development needs/goals?
- How would the IP provisions envisaged by the US affect access to treatment for PLWH/A and the cost of treatment?
- How would the US template limit TRIPS flexibilities e.g. Lesotho is an LDC, has no obligations for pharmaceutical patents until 2016.

Possible TRIPS-plus provisions in the FTA

USTR's formal notification to congress contains certain objectives:

- Seeks to establish standards the reflect protection similar to US law
- Build on foundations established in TRIPS, and WIPO Copyright Treaty, Patent Cooperation Treaty → i.e. WTO-plus
- Establish commitments for SACU countries to strengthen their domestic enforcement procedures, includes → criminal proceedings and penalties with deterrent effect, seizure of suspected pirated and counterfeit goods, and equipment used to make or transmit there goods, documentary evidence
- Strengthen SACU measures for compensating right holders for infringement of IP rights
- BUT USTR not clear in what going beyond the minimum TRIPS standards means? Do definitions of piracy and copyright apply to pharmaceuticals?
- However, reference to pharmaceuticals does not necessarily affect access
- Protect against counterfeit to ensure quality, safety and efficacy
- Piracy provisions and sanctions likely to be directed at copyright and related rights

Possible TRIPS-plus provisions in the FTA

- USTR tries to mitigate provisions on access e.g. side letters in Morocco FTA → follo language of Doha Declaration on TRIPS & Public Health, suggests FTA provisions c be used to promote access:
  - Obligations set out in the IP Chapter *"do not affect the ability of either Party to ta necessary measures to protect public health by promoting access to medicines f all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency"*
- Effect depends on legal status of the side letters
- Few problematic issues from previous US FTAs which threaten access to a sustainable supply of affordable essential medicines in SACU:
  - Although IP provisions might not be retrospective, they appear to 'upgrade' existing patent rights in a manner that was not anticipated when rights initially granted
  - Do not appear to allow recourse to full range of exceptions permitted under Artic 27 of TRIPs → restricted to Article 27.2 (measures to protect *ordre public* or morality, including to protect human, animal or plant life or health or environment
  - Excludes Article 27.3(a) exceptions that deal with diagnostic, therapeutic & surgical methods for the treatment of humans or animals

Possible TRIPS-plus provisions in the FTA

- Patents should …"be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals" → Appear to require 'second-use' patents on products that are no longer under patent for their original first use. This can limit access without corresponding innovative benefit. E.g. AZT. Problematic that SA law already for this.
- Precluding parallel trade in patented products is TRIPS-plus and could proscribe use of compulsory licensing to local production forcing recourse to the cumbersome provisions of the August 30 Agreement.
- US provision that 'patents may only be revoked on grounds that would have justified a refusal to grant the patent'. This precludes measures to provide for forfeiture of the patent in cases where the grant of compulsory license is insufficient to prevent abuse that can arise from the exercise of patent rights (Article 2.1 of TRIPS, Article 5A(3) of the Paris Convention) → DR-CAFTA retains Article 5A(3)
- US provisions that allow extension of patent term to compensate for unreasonable delays in granting the patent → could limit access to essential medicines, and faster procedures could limit opportunity for pre-grant opposition.

Possible TRIPS-plus provisions in the FTA

- US requirements to prevent strict disclosure requirement by patent applicant (5 yrs data protection in the case of products with new chemical entities) can delay entry of generic products (affecting access and costs) and raise the costs of search for material → Entrenched in DR-CAFTA
- Provisions that limit the ability of health providers/government to extract price reductions from patent holders (e.g. Aus/US FTA Pharmaceutical Benefits Scheme)
- There are other non-IP issues that could limit access to essential medicines and health care services such as provisions on trade in services (health and possibly financial), investment (through creating the possibility of investor/state disputes, i.e. being sued for lost profits or failing to implement and enforce IP provisions in the FTA, which might concern the BLNS), procurement (for example, cumbersome tendering procedures affecting the ability to deal with health emergencies).
- Copyright concerns e.g. regarding extended copyright periods, restrictions on translation or adaptation, and affordable access to information and learning materials through various media formats from educational institutions and libraries; includes materials for the disabled, distance learning etc

Concluding Remarks

- US likely to focus on limiting the scope of compulsory licensing; limiting grounds for patent revocation; new use patents; long period of data exclusivity; limiting parallel trade; patent extension to compensate registration delays; policing role for regulator
- Limitations on parallel imports; compulsory licensing; extended patent protection periods and data exclusivity periods will affect the ability of SACU countries to procur and provide essential medicines
- Difficult to say with absolute certainty what SACU position is, in particular South Afric
- SACU has been largely defensive on IP → tries to limit US demands
- SA law in some respects already incorporates some TRIPS-plus provisions e.g. Patents Act (1978) does not make full use of regulatory tools like compulsory licensir as envisaged in Doha Declaration or deal effectively with health emergencies.
- But adopting the US template will mean significant changes in domestic legislation
- SACU needs to maintain flexibility to have recourse to compulsory licensing and to adopt measures that can prevent anti-competitive practices (resulting from abuse of IPRs). E.g. Art 15.1.5 of DR-CAFTA and Art 17.1.13 of Chile FTA.
- These are the essential means of ensuring a commitment to license generic manufacturers to supply the region.
- SACU must develop and strengthen regional competition policy
- Benefit from experience of other countries that have engaged the US

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Thank You