THE REVISED DRAFT IP POLICY, POLICY COHERENCE AND HUMAN RIGHTS ASSESSMENT

Prof. Frederick M. Abbott

FSU College of Law/UNDP Consultant

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The HLP Report and Balance

- South Africa and its many stakeholder groups represent various interests in the intellectual property system
- The HLP Report recognizes that tensions exist among stakeholder interests and demands, and seeks to achieve an appropriate balance. It also recognizes that the balance may be different in different country settings, and among different social and economic groups
- Whenever a balancing is undertaken, it is not going to satisfy each stakeholder because that stakeholder's most preferred position will not be achieved

Industry and Society

- South Africa has substantial pharmaceutical/biomedical/import-export and formulation industry concerned about security of investment, and promoting a receptive environment. The structuring of the IP system is relevant to that, though one among a variety of factors, such as currency stability and regulatory predictability
- South Africa has both ordinary and extraordinary demands on its health care system, and concomitant human rights interests, and budgetary interests. Affordability and access to medicines and healthcare more generally are critical matters for South Africa and its policy community. The appropriate balance among stakeholder interests in South Africa is going to be unique to South Africa, even if it may be similar to the balance in countries in similar circumstances

The HLP, Human Rights and Draft IP Policy

- The draft IP Policy, consistent with the HLP Report, takes into account in a strong way the human rights element, alongside the trade and economic elements. Each of the recommendations made in the draft IP Policy appears to be consistent with the recommendations of the HLP, although it remains to carry these recommendations into specific legislative language and practice
- Human rights instruments and interpretations confirm *priority* for promotion and protection of *life and health as core obligation*
  - Protection of interests in authors' creative works recognized, but subject to appropriate balancing
- This does not mean that the draft IP Policy goes as far as it might in respect of any stakeholder group, which is implicit in the concept of balance

Substantive Patent Examination and Criteria

- SSE necessary to guard against grant of spurious and/or undeserving patents that unnecessarily block access and affordability
  - Fulfills bargain between inventor and society
  - Progressive implementation beginning with pharmaceutical field appropriate
- Each patentability criterion includes internal balance that should favor strict demand for inventive contribution
- Details regarding adequate description of invention important

Third Party Observations and Post-Grant Opposition, track to Pre-Grant Opposition

- Third party observation largely cost-free manner of improving search capability
- Post-grant opposition substantially reduces social burden by allowing for prompt culling of improvidently granted patents; expands interested challengers and eliminates requirement for party controversy; traditionally more cost-effective than civil litigation
  - Preferably through administrative process, but here transitional
- Pre-grant opposition shown to be effective in India
  - Sophisticated NGOs capable of reducing strains on healthcare budget

Regulatory Review (Bolar) Exception and Research Exception

- Important to accelerating introduction of generics
  - Approved by WTO panel, widely adopted
  - South Africa: Section 69A of the Patents Act No. 57 of 1978 (as last amended by Act No. 58 of 2002)
- Research exemption provides mechanism to explore alternative means to achieve comparable results
- In U.S. Patent Act regulatory review exception covers both regulatory review and early research (*e.g.*, pre-clinical) pathway (see *Merck v. Integra Lifesciences*, 545 U.S. 193 (2005)

Compulsory Licensing

- Important alternative to voluntary licensing
  - Absence of effective compulsory licensing alternative substantially constrains third-party/government bargaining power
- Compulsory licensing should be available for all essential medicines with fast-track
- Critical element is efficient administrative process with appropriate time-lines; multiyear litigation process effectively defeats the purpose of compulsory licensing

Government Use Licensing

- An essential component of national health security
- South Africa existing requirement of application to Patent Commissioner a burdensome impediment
  - Compare U.S. automatic government use
- Draft policy appropriately calls for reform

Parallel Importation

- Expressly authorized in favor of Minister of Health
- Patent Act should be interpreted to authorize generally
- See recent US Supreme Court decision interpreting US Patent Act to authorize parallel importation (*Impression Products v. Lexmark Internation*al, 581 U.S. ___ (2017)) - confirms Medicines Act flexibility defended by South Africa

Transparency

- Essential to protecting public interests
- Required disclosure of medicine covered by patent(s)
- Disclosure of R&D costs important to various policies; increasingly demanded by legislative efforts, including to justify price increases
- Clinical trial data important to assure integrity of approval processes

IP and Competition

- Absolutely essential to balanced patent system
- Patents capable of misuse in various ways, most commonly to delay generic entry
  - Week or sham secondary patents, buy-outs, product switching
- Excessive pricing
- Anticompetitive behaviors affect generics markets as well

Promotion of Local Production

- May aid in sustaining medicines security
- Important to national science and technology development
  - Employment opportunities in chemistry, biotechnology, software development and other sciences
- Requires mechanisms for technology transfer
- Encouraged by WHO

Avoidance of IP commitments in trade and investment agreements

- Rarely designed to reflect progressive social welfare policy
- Inhibit government flexibility to address public health problems and promote access for all
- Governments retain authority to regulate as national interest befits

Inter-Ministerial Committee on IP

- South Africa a leader on governmental coordination
- Consistent with HLP recommendation of policy coherence
- Important to maintain in focus core human rights obligation to promote and protect life and health