SESSION 4
ACCESS TO MEDICINE: COMMERCIALISATION, DISTRIBUTION, COMPETITION

Exploitation of pharmaceutical patents: compulsory licences

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SETTING THE SCENE:

WHY IS COMPULSORY LICENSING RELEVANT TO PHARMACEUTICAL PATENTS?
health issues and access to affordable medicines are always high on the agenda of most international deliberations involving patents in recent years

- the nature and extent of the burden of disease, particularly amongst poor populations
- the need to address public health crises caused by pandemic diseases, particularly in poor countries
- the need to address also neglected or ‘third world’ diseases particularly prevalent in poor countries
- the need to provide effective and affordable medicines
- the role of patents in facilitating/frustrating access to effective and affordable medicines
these deliberations reflect a continuous debate between developing and developed countries regarding the interface between IP rights and a variety of public interest issues

- public health and the impact of patents in the context of pandemic diseases
- low levels of technology transfer and the need for increased research and enhancement of industrial capacity
- need for economic growth and the perception that IP mainly benefits developed countries
- value of indigenous knowledge and lack of IP protection
- biodiversity and the abuse of biological/genetic resources without benefit to indigenous communities
The following line of argument is used by some NGOs and by some countries in the public health debate:

- The health crises in developing and least-developed countries are caused by pandemic and endemic third world diseases.
- New medicines for these diseases are not sought and developed; pharmaceutical companies focus on sophisticated diseases for R&D costs to be recovered.
- If new medicines for these diseases, e.g., for HIV/AIDS, are found they are under patents which grant exclusive rights.
- This means that manufacturing and distribution rights are exclusive to the patent owner – are ‘monopolised’.
- The result is a pricing system making these medicines unaffordable and inaccessible to poor people.

One perception is that compulsory licences could resolve some issues.
to address this question from a legal perspective, and to come up with an answer in a South African context, it is necessary to consider the applicable provisions in our law

- do patents grant exclusive rights (monopolies), and are there limits to these rights?
- do patents prevent third parties from making and selling patented medicines? and generic equivalents?
- can third parties (generics manufacturers) obtain user or manufacturing rights in respect of patented medicines?
- does the law provide for the State to step in and make use of patents, eg to source cheaper medicines?
- are there other legal mechanisms that may be used to obtain user or manufacturing rights?
- would access to medicines be ensured and the health crises be resolved in the absence of patents?
THE PLAYERS AND THE SEARCH FOR SOLUTIONS

- the current debates, and the search for solutions, involve three world players
  - WHO is committed to the promotion and implementation of health care, and is mandated to identify and address global health problems, to improve the well-being of people through medical, research and information initiatives, to ensure that IP regimes stimulate research for new cures
  - WTO is committed to promoting and facilitating international trade, through reducing distortions and impediments to international trade, and by ensuring that IP rights are subject to flexibilities and do not become barriers to legitimate trade
  - WIPO is committed to the promotion, protection and legitimate use of IP, to ensure that IP stimulates research and contributes to economic growth and technological advancement through advisory, collaborative and administrative initiatives
all three world players have issued instruments proposing solutions involving pharmaceutical patents

- **WHO: Report on Public Health, Innovation and IP (CIPIH)**
  - recognised the magnitude of the burden of disease
  - encouraged public/private partnership, research funding
  - suggested government actions, eg patent buy-outs, purchase price leverage, parallel imports
  - urged use of TRIPS flexibilities, voluntary licences, compulsory licences

- **WTO: Doha Declaration**
  - recognised the gravity of public health problems
  - recognised the importance of patents to encourage research for development of new medicines
  - recognised government power to declare national emergencies, grant compulsory licences, make use of TRIPS flexibilities
  - agreed on dual compulsory licence model, waiving certain obligations
WIPO: Development Agenda
- recommended that IP enforcement take account of social needs
- urged dissemination of information and transfer of technology
- encouraged enhancement of accessible public domain to provide a source of information
- encouraged fair balance between IP protection and public interest

SOUTH AFRICA: which of these proposals have been implemented?
- provision for compulsory licences?
- provision for pharma-specific licensing model?
- intervention by the State, parallel importation?
- provision for other mechanisms, eg anti-competitive measures?
- projects for public/private partnerships, technology transfer?
ONE POSSIBLE ROUTE:

PROVISION FOR COMPULSORY LICENCES AND DUAL LICENCE MODEL
Patents Act, 1978 s 45 grants to the patent owner the right to exclude others from making, using, exercising, disposing of, or importing the patented invention so that the patent owner shall have and enjoy the whole profit and advantage accruing by reason of the invention.

The patent owner can decide to exercise his rights by the grant of voluntary licences.

- This makes the patented product available to the public but the terms and conditions depend on the will/decision of the patent owner.

The patent owner can also be compelled to exercise his rights by the grant of compulsory licences.

- This also makes the patented product available to the public but the terms and conditions are determined by the Court/State.
TRIPS Art 31: member countries may allow use of the subject of a patent by government or third parties without authorisation of patent owner

- this contemplates use by way of compulsory licences
- strict conditions prescribed for granting of licences
- strict rules prescribed for exercise of licences

Art 31 does not provide the solution for the health crises in developing countries and LDCs

- Art 31(f): licence predominantly for supply of domestic market; no exports permitted
- Art 31(h): right holder to be paid adequate royalty, taking into account economic value of licence
- so, compulsory licence will only assist countries with manufacturing capacity; and risk of double royalty
Patents Act, 1978 s 56 allows for compulsory licences in cases of abuse of patent rights

- s 56 substantially in line with TRIPS Art 31
- patent rights deemed to be abused if the demand for the patented product is not being met to an adequate extent and on reasonable terms
- patent rights deemed to be abused if local demand for patented product is being met by importation and local price is excessive in relation to price in other countries
- s 56 requires court application and consideration, and thus disclosure of all relevant facts, also possibly confidential facts
- so far no compulsory licence has been granted in SA under s 56 for medicinal products
the Doha Declaration of WTO/TRIPS recognises the shortcomings of Art 31 for countries with no capacity to manufacture; TRIPS Council to find solution

in 2005 WTO reached agreement on a dual licensing model applicable to –

- ‘pharmaceutical product’ ie any patented product or product of a patented process required to address public health problems, particularly arising from the pandemic diseases

- ‘eligible importing country’ is any least-developed or developing country which has lodged a notification of use based on insufficient manufacturing capacity

- ‘exporting country’ is a country using the system to manufacture pharmaceutical products for export to eligible importing countries
DOHA PROVIDES NEW MODEL FOR COMPULSORY LICENCES

- Dual compulsory licence model envisages that –
  - Exporting country grants compulsory licence for manufacture and export subject to certain conditions
  - Art 31(f) restriction on export waived
  - Eligible importing country grants a compulsory licence for importation if product patented there
  - Art 31(h) adequate royalty paid for licence in exporting country; obligation to pay waived for importing country
  - Eligible importing country to prevent re-exportation of product (except to other LDCs or developing countries in regional trade agreements, e.g., SADC)
  - TRIPS Council to be notified and to monitor system
  - TRIPS Agreement to be amended by insertion of Art 31 bis to provide for system
IMPLEMENTATION OF DOHA LICENSING MODEL

- early indications of extent of implementation of Doha dual licensing model into national laws
  - implementing legislation enacted in Canada, India, Indonesia, Korea, Mexico, Norway
  - implementing legislation in progress in EU, France, Sweden, Switzerland
  - implementing measures being considered in Brazil, Bulgaria

- some developed countries have indicated that they will not use the system as importing countries
  - these include Australia, Canada, France, Germany, Italy, Japan, Netherlands, New Zealand, Switzerland, UK, USA

- South Africa has not yet implemented the dual licensing model in the national law
ANOTHER POSSIBLE ROUTE:

PROVISION FOR SPECIAL EXCEPTIONS OR SPECIAL MEASURES RELATING TO PATENT RIGHTS
TRIPS ALLOWS EXCEPTIONS TO PATENT RIGHTS

- TRIPS Art 30 allows member countries to provide for limited exceptions to the exclusive rights of patents
  - legitimate interests of third parties to be taken into account
  - this provision accepted as basis for early working provision (Bolar provision) to permit generic substitutes to obtain marketing approval during term of patent of original medicine

- Patents Act, 1978 s 69A introduced a Bolar provision
  - permits non-commercial use, exercise, or importation of patented subject matter by others (generics manufacturers) solely for the purpose of developing information for regulatory approval of a product
  - early market access for generic equivalents facilitated
  - prohibits possession for other purposes (ie stockpiling)

- this is an example of use of a TRIPS flexibility
TRIPS ALLOWS SPECIAL MEASURES RELATING TO PATENT RIGHTS

- TRIPS Art 8.1 allows special measures to protect public health; measures to be consistent with TRIPS
- TRIPS Art 6 permits parallel importation of products
- Medicines Act, 1965 s 15C gives Minister (of Health) certain powers for the supply of more affordable medicines to protect public health
  - Minister may permit importation of a medicine by persons other than patent holder, if medicine is of identical composition and quality and originates from original site of manufacture
  - Generally accepted this enables parallel importation (ie of genuine medicines) to be authorised
  - Medicine imported and registered may only be sold to state or authorised seller
  - Objective is for genuine medicines to be sourced at more favourable negotiated pricing
YET ANOTHER POSSIBLE ROUTE:

PROVISION FOR SPECIAL MEASURES TO PREVENT ABUSE OF PATENT RIGHTS
TRIPS ALLOWS MEASURES TO PREVENT ABUSE OF PATENT RIGHTS

- **TRIPS Art 8.2**: countries may adopt appropriate measures to prevent abuse of IP rights by rights holders; measures to be consistent with TRIPS
  - no indication of conduct that would constitute abuse of rights, or of the nature of measures
  - reference is made to practices which unreasonably restrain trade, i.e., anti-competitive practices

- **Competition Act, 1998 s 6** prohibits a dominant firm to abuse its dominant position by engaging in certain anti-competitive practices
  - to charge an excessive price to the detriment of consumers
  - to refuse to give a competitor access to an essential facility
  - to engage in an exclusionary act if the anti-competitive effect thereof outweighs its pro-competitive gains

- the Competition Act applies to all economic activity and overrides the Patents Act
a complaint was lodged with the Competition Commission that certain pharmaceutical companies contravene s 6 by abusing their dominant positions

- the complaint was based on the refusal by the companies to grant voluntary licences under their patents for anti-retroviral drugs to generic manufacturers on reasonable terms

- before the matter was heard by the Competition Tribunal, a settlement was reached and licences were granted

- the licences permitted local manufacture, importation for distribution in South Africa, and exportation to sub-Saharan African countries

- these provisions echo the principles of TRIPS Art 31 bis
IN CONCLUSION:

THE WAY TOWARDS FINDING WORKABLE SOLUTIONS
in the search for solutions to public health crises, the diversity of the issues should be acknowledged

- the flexibility of international IP rules should be recognised; countries are permitted to introduce the necessary measures to protect public health and to address national needs

- affordable supply channels for medicines should be established; many developing countries and LDCs lack manufacturing capacity to manufacture medicines, even if they were permitted to do so

- effective healthcare structures should be established; many developing countries and LDCs lack adequate medicine distribution facilities to administer certain medicines, even if they had access to those medicines
it is imperative that solutions be found for current health crises and to ensure access to medicines

- must be balanced, feasible, effective and enduring

it is suggested that a three-pronged approach is necessary to achieve solutions

- provision of an IP legislative/regulatory framework and appropriate legal measures, using TRIPS flexibilities
- collaborative initiatives with pharmaceutical companies
  - on prices, eg for government procurement
  - on supply, eg for countries in greatest need
  - on search for better cures, also for neglected diseases
- government measures to ensure improvement of and access to healthcare infrastructure
Thank you for your attention
Questions?