INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

THE INTERNATIONAL SCENE

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THE INTERNATIONAL SCENE:

International instruments, norms and initiatives relevant to IP Rights and the Pharmaceutical Industry
this session will focus on international instruments, norms and initiatives of direct relevance to intellectual property and the pharmaceutical industry

health issues formed part 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 provide effective and affordable medicines
- the role of patents in facilitating/frustrating access to effective and affordable medicines

these deliberations reflect a growing tension between developing and developed countries regarding the interface between IP rights and a variety of issues impacting on public health

- public health and the impact of patents on the access to medicines in the context of pandemic diseases
- low levels of technology transfer in the pharmaceutical sector and a need for increased manufacturing capacity
- value of indigenous knowledge in regard to traditional remedies and lack of IP protection for TK
- the use/abuse of indigenous biological and genetic resources in the development of new medicines, without benefit to indigenous communities for their traditional knowledge and healing methods
SETTING THE SCENE

- questions are also raised regarding the value – and constraints – of IP treaties and conventions to developing and least-developed countries (LDCs)
  - developing countries and LDCs are part of the international IP and trade community
  - it is recognised that if solutions are to be found for the issues raised, they should be sought within the trade, health support and IP systems of WTO, WHO and WIPO
- do the WTO/WHO/WIPO systems permit joint efforts by governments and public and private sector corporations to find beneficial solutions to the public health/patent challenge?
  - that is the question that must be addressed

THE SYSTEM AND THE PLAYERS

- the World Trade Organisation (WTO) is an intergovernmental body created by agreement to focus on trade and trade-related issues
  - WTO was established in 1994, after more than a decade of negotiations; currently 151 member countries, 41 African countries
  - SA was a signatory of WTO/TRIPS in 1994
  - WTO/TRIPS (Agreement on Trade-Related aspects of IP Rights) is one of the instruments establishing WTO
  - TRIPS prescribes minimum levels of protection for IP and regulates the exploitation of IP
  - TRIPS came into force on 1 Jan 1995; it is primarily a trade instrument, addresses wider trade-related issues
  - TRIPS has a dispute resolution mechanism; possible trade sanctions ensure adherence to WTO treaties
THE SYSTEM AND THE PLAYERS

- the World Intellectual Property Organisation (WIPO), an agency of the UN, is traditionally responsible for IP and international IP treaties
  - WIPO was established in 1967 but its predecessor, BIRPI was formed in 1893; currently 182 member countries, 49 are African countries
  - SA became a member in 1967
- WIPO treaties confirm the need for protecting IP and for recognising IP rights
  - treaties generally lack enforcement mechanisms; WIPO established a mediation centre to deal with disputes
  - WIPO and WTO recognised that cooperation was desirable and concluded a collaboration agreement in regard to IP

THE SYSTEM AND THE PLAYERS

- the World Health Organisation (WHO), like WIPO, is a UN body set up to direct and coordinate international health operations
  - WHO was established in 1948; currently has 193 member states, 48 are African countries
  - SA is a member state
- WHO formulates health standards and guidelines, addresses public health issues and promotes research
  - in 2003 set up the Commission on IP Rights, Innovation and Public Health (CIPIH) to consider relationship between IP rights, innovation and public health
  - published comprehensive report in 2006 with list of recommendations
  - gave rise to drafting WHO Global Strategy and Plan of Action
THE SYSTEM AND THE PLAYERS

- summarising the focus of these three world players:
  - WIPO is committed to the promotion, protection and legitimate use of IP, to ensure that IP contributes to economic growth and technological advancement through advisory, collaborative and administrative initiatives
  - WHO is committed to the promotion and implementation of health care, and mandated to identify and address global health problems, to improve the well-being of people through medical, research and information initiatives, ensuring 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, ensuring that IP rights do not become barriers to legitimate trade

IP AND PUBLIC HEALTH: CHALLENGES AND ISSUES

- the following line of argument is used by some NGOs and countries in the public health debate
  - the health crises in developing countries and LDCs 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, eg 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
lack of effective treatment of pandemic diseases is thus blamed on lack of access to affordable medicines, in turn blamed on the existence of patents, with arguments that –

- patent rights are exclusionary and monopolistic
- patent rights give rise to excessive drug prices
- patent rights keep out cheaper generic substitutes
- patent rights do not promote technology transfer
- world-wide patent coverage hampers parallel importation
- patent owners are unwilling to grant voluntary licences
- pharmaceutical industry is not actively seeking cures for neglected diseases

The challenges by developing countries within WTO, WHO and WIPO regarding health issues and the effects of IP protection systems cannot be disregarded

- the majority, ie about 120, of the 151 WTO member states are developing and least-developed countries (LDCs); 41 are African countries
- the majority of the 193 WHO member countries are developing countries and LDCs; 48 are African countries
- the majority of the 182 WIPO member countries are developing countries and LDCs; 49 are African countries
- developing countries have formed several negotiating blocks to present united positions to WTO/WHO/WIPO
- clearly numerical weight is on the side of developing countries and LDCs; economic power and technology advancement on the side of the developed countries
IP AND PUBLIC HEALTH: CHALLENGES AND ISSUES

- in the challenges around patents and the burden of disease in developing countries and LDCs, the following players cannot be disregarded
  - the poorest populations (one third of world population) which suffer two thirds of the world’s disease burden
  - the governments in developing countries and LDCs, responsible for providing essential health care
  - pharma companies which invest heavily in R&D and product development to provide new drugs
  - government agencies in developing countries and LDCs are big buyers of medicines and have negotiating power
  - the research institutions which have to seek and develop cures also for so-called neglected diseases
- the challenge is to find solutions which will be effective, affordable, sustainable and legitimate

SEARCH FOR SOLUTIONS: INITIATIVES BY WIPO

- in response to the needs of developing countries and LDCs, WIPO in 2007 established its Development Agenda with 45 agreed proposals
  - to make available to developing countries and LDCs, within the framework of the WTO/WIPO agreement, advice on the use of TRIPS flexibilities
  - to preserve and promote the benefits of a rich and accessible “public domain” of accessible information
  - to urge its Intergovernmental Committee (IGC) to accelerate the protection of genetic and biological resources and TK, including traditional medication
  - to facilitate and enhance cooperation and exchange of information by research and development institutions in developed and developing countries
  - to identify cooperation initiatives on IP-related matters with other UN agencies, including WHO and WTO
### SEARCH FOR SOLUTIONS: INITIATIVES BY WIPO

- **WIPO provides a well-positioned international forum to identify needs relating to IP rights**
  - the need for compulsory licences for non-working
  - the need to provide protection for indigenous biological resources and related TK
- **WIPO is prepared to cooperate with other players**
  - WIPO is identified by CIPIH report of WHO for collaboration to promote patent pools of upstream technologies to address diseases disproportionately affecting developing countries
  - WIPO and WTO recognised that cooperation was desirable, concluded a collaboration agreement on IP

### SEARCH FOR SOLUTIONS: INITIATIVES BY WHO

- **in 2003 World Health Assembly (WHA) passed resolution WHA 56.27 to set up the Commission on IP Innovation and Health**
  - to collect data and produce an analysis of IP rights, innovation and public health, including necessary funding and incentive mechanisms to create new medicines against diseases that disproportionately affect developing countries
- **CIPIH report published in 2006; several recommendations relate to IP**
  - recognises that the patent system has an incentive function and a disclosure function
  - research tools and platform technologies to be maximised, better use of universities and research bodies in health area
  - better use of patent pools, compulsory licensing mechanisms
  - recognises that developing countries have a rich source of medical traditional knowledge, and medical properties of plants
following on the CIPIH report, the WHA in May 2006 passed resolution 59.24 recognising that
- the world is facing a growing burden of diseases disproportionately affecting developing countries
- safe and affordable new products to treat these diseases must be developed
- advances in biomedical science to be harnessed
- IP rights can be beneficial, offer incentives for research
- member countries urged to make global health and access to medicines a priority
- the Intergovernmental Working Group (IGWG) established; objective of preparing a global strategy and plan of action to implement the recommendations

public health issues and access to medicines dominated the 2001 WTO Meeting in Doha, Qatar
- the proceedings were characterised by serious confrontation between countries on the issue of the public health crisis
- WTO Council issued the Doha Declaration on Public Health in 2001, recognising –
  - the gravity of public health problems (HIV/AIDS, TB, Malaria) afflicting developing and least-developed countries
  - IP protection is important for development of new medicines, to counterbalance the substantial R&D investment
  - that there are concerns regarding the effect of IP protection on pricing of medicines
  - that TRIPS does not prevent member countries to protect public health and gain access to affordable medicines
  - that WTO/TRIPS initiative is part of a wider international action to address public health problems
the Doha Declaration further confirmed
- that member countries have the right to grant compulsory licences and to determine the grounds on which licences are granted
- that member countries have the right to determine what constitutes a national emergency; public health crises can constitute a national emergency
- that TRIPS leaves it to member countries to establish their own position on exhaustion of rights and legitimacy of parallel importation
- that member countries without manufacturing capacity faced difficulty in using compulsory licensing
- that TRIPS Council must find an expeditious solution by 2002 for a manufacturing licence system to provide cheaper medicines to developing countries and LDCs

the WTO Ministerial Meeting in Hong Kong in 2005 approved the amendment of TRIPS by the insertion of Art 31bis
- eligible importing country will grant a compulsory licence if product is patented in that country
- exporting country will grant compulsory licence for manufacture and exportation
- adequate remuneration to be paid for licence in exporting country; obligation to pay remuneration for licence waived for importing country
- eligible importing country will provide measures to prevent re-exportation of product (except to LDCs or other developing countries in regional trade agreements)
- TRIPS Council to be notified of licences granted and to monitor system
SEARCH FOR SOLUTIONS: INITIATIVES BY WTO

- early indications of extent of implementation of Doha licensing model into national laws
  - implementing legislation has been enacted in Canada, Mexico, Norway
  - implementing legislation is in progress in EU, Indonesia, Korea, Sweden, Switzerland
  - implementing measures are being considered in Brazil, Bulgaria, France
  - SA has not yet passed legislation to implement the provisions of Art 31bis
  - some developing countries have notified WTO that they may use system as importing countries, including South Africa, Botswana, Brazil, China, Egypt, Ghana, India, Kenya, Namibia, Nigeria, Swaziland and Zimbabwe

IN CONCLUSION

- in the search for solutions to public health crises, the diversity of the issues must be acknowledged
  - the flexibilities in TRIPS should be recognised, permitting countries to use measures to protect public health and to address national needs and emergencies
  - affordable supply channels for medicines should be established; many developing countries and LDCs lack manufacturing capacity for medicines, even if permitted to do so, and supply must be from outside
  - effective healthcare structures should be established; many developing countries and LDCs lack adequate medicine distribution facilities even if they had access to those medicines
  - above all, to be effective the solution will have to be balanced, affordable, feasible – and should not be a disincentive to innovation
Thank you for your attention

Questions?