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**INTELLECTUAL PROPERTY RIGHTS
AND
PHARMACEUTICAL PRODUCTS
AND PROCEDURES**

THE INTERNATIONAL SCENE
by
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**INTELLECTUAL PROPERTY RIGHTS AND
PHARMACEUTICAL PRODUCTS AND PROCEDURES**

THE INTERNATIONAL SCENE:
**International instruments, norms and
initiatives relevant to
IP Rights and the Pharmaceutical Industry**

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SETTING THE SCENE</h2> <ul style="list-style-type: none">■ 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<ul style="list-style-type: none">❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SETTING THE SCENE</h2> <ul style="list-style-type: none">■ 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<ul style="list-style-type: none">❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SETTING THE SCENE</h2> <ul style="list-style-type: none"> ■ questions are also raised regarding the value – and constraints – of IP treaties and conventions to developing and least-developed countries (LDCs) <ul style="list-style-type: none"> ❖ 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? <ul style="list-style-type: none"> ➤ that is the question that must be addressed

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">THE SYSTEM AND THE PLAYERS</h2> <ul style="list-style-type: none"> ■ the World Trade Organisation (WTO) is an intergovernmental body created by agreement to focus on trade and trade-related issues <ul style="list-style-type: none"> ❖ 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

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THE SYSTEM AND THE PLAYERS

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- 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

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THE SYSTEM AND THE PLAYERS

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- 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 (CIPRH) 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">THE SYSTEM AND THE PLAYERS</h2> <ul style="list-style-type: none"> ■ summarising the focus of these three world players: <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">IP AND PUBLIC HEALTH: CHALLENGES AND ISSUES</h2> <ul style="list-style-type: none"> ■ the following line of argument is used by some NGOs and countries in the public health debate <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">IP AND PUBLIC HEALTH: CHALLENGES AND ISSUES</h2> <ul style="list-style-type: none"> ■ 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 – <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">IP AND PUBLIC HEALTH: CHALLENGES AND ISSUES</h2> <ul style="list-style-type: none"> ■ the challenges by developing countries within WTO, WHO and WIPO regarding health issues and the effects of IP protection systems cannot be disregarded <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center; color: yellow;">IP AND PUBLIC HEALTH: CHALLENGES AND ISSUES</h2> <ul style="list-style-type: none"> ■ in the challenges around patents and the burden of disease in developing countries and LDCs, the following players cannot be disregarded <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center; color: yellow;">SEARCH FOR SOLUTIONS: INITIATIVES BY WIPO</h2> <ul style="list-style-type: none"> ■ in response to the needs of developing countries and LDCs, WIPO in 2007 established its Development Agenda with 45 agreed proposals <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SEARCH FOR SOLUTIONS: INITIATIVES BY WIPO</h2> <ul style="list-style-type: none"> ■ WIPO provides a well-positioned international forum to identify needs relating to IP rights <ul style="list-style-type: none"> ❖ 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 <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SEARCH FOR SOLUTIONS: INITIATIVES BY WHO</h2> <ul style="list-style-type: none"> ■ in 2003 World Health Assembly (WHA) passed resolution WHA 56.27 to set up the Commission on IP Innovation and Health <ul style="list-style-type: none"> ❖ 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 <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SEARCH FOR SOLUTIONS: INITIATIVES BY WHO</h2> <ul style="list-style-type: none"> ■ following on the CIPIH report, the WHA in May 2006 passed resolution 59.24 recognising that <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SEARCH FOR SOLUTIONS: INITIATIVES BY WTO</h2> <ul style="list-style-type: none"> ■ public health issues and access to medicines dominated the 2001 WTO Meeting in Doha, Qatar <ul style="list-style-type: none"> ❖ 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 – <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SEARCH FOR SOLUTIONS: INITIATIVES BY WTO</h2> <ul style="list-style-type: none"> ■ the Doha Declaration further confirmed <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SEARCH FOR SOLUTIONS: INITIATIVES BY WTO</h2> <ul style="list-style-type: none"> ■ the WTO Ministerial Meeting in Hong Kong in 2005 approved the amendment of TRIPS by the insertion of Art 31 <i>bis</i> <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SEARCH FOR SOLUTIONS: INITIATIVES BY WTO</h2> <ul style="list-style-type: none"> ■ early indications of extent of implementation of Doha licensing model into national laws <ul style="list-style-type: none"> ❖ 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 31<i>bis</i> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">IN CONCLUSION</h2> <ul style="list-style-type: none"> ■ in the search for solutions to public health crises, the diversity of the issues must be acknowledged <ul style="list-style-type: none"> ❖ 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

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**Thank you for
your attention
Questions?**