




**Adams & Adams**  
Intellectual Property Specialists



**2009**



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CONTINUING EDUCATION  
UNIVERSITY OF PRETORIA

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# TRAINING COURSE

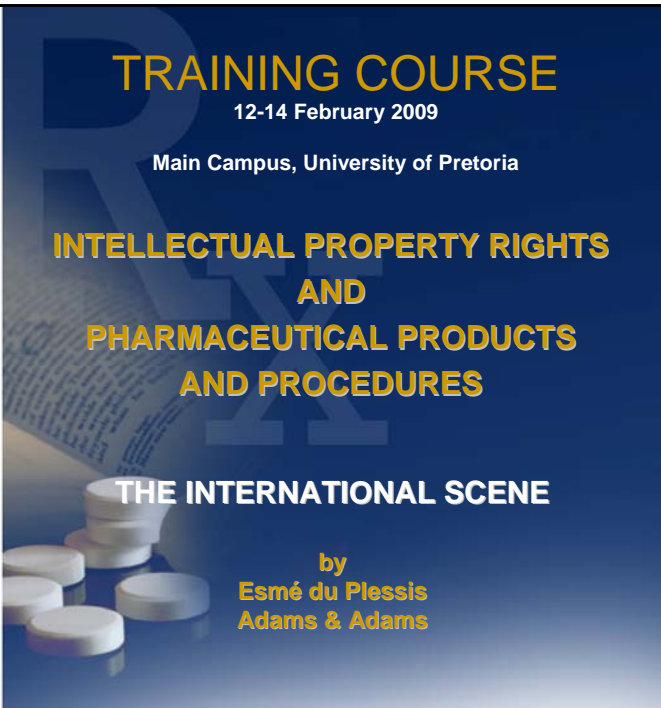
12-14 February 2009

Main Campus, University of Pretoria

## INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

### THE INTERNATIONAL SCENE

by  
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INTELLECTUAL PROPERTY RIGHTS AND  
PHARMACEUTICAL PRODUCTS AND PROCEDURES

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## THE INTERNATIONAL SCENE:

### International instruments, norms and initiatives relevant to IP Rights and the Pharmaceutical Industry

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<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<h2 style="text-align: center;">SETTING THE SCENE</h2> <ul style="list-style-type: none"> <li>■ this session will focus on international instruments, norms and initiatives of direct relevance to intellectual property and the pharmaceutical industry</li> <li>■ health issues formed part of most international deliberations involving patents in recent years <ul style="list-style-type: none"> <li>❖ the nature and extent of the burden of disease, particularly amongst poor populations</li> <li>❖ the need to address public health crises caused by pandemic diseases, particularly in poor countries</li> <li>❖ the need to provide effective and affordable medicines</li> <li>❖ the role of patents in facilitating/frustrating access to effective and affordable medicines</li> </ul> </li> </ul>

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<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<h2 style="text-align: center;">SETTING THE SCENE</h2> <ul style="list-style-type: none"> <li>■ 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"> <li>❖ public health and the impact of patents on the access to medicines in the context of pandemic diseases</li> <li>❖ low levels of technology transfer in the pharmaceutical sector and a need for increased manufacturing capacity</li> <li>❖ value of indigenous knowledge in regard to traditional remedies and lack of IP protection for TK</li> <li>❖ 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</li> </ul> </li> </ul>

## 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

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

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<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<h2 style="text-align: center;">IP AND PUBLIC HEALTH: CHALLENGES AND ISSUES</h2> <ul style="list-style-type: none"> <li>■ the following line of argument is used by some NGOs and countries in the public health debate           <ul style="list-style-type: none"> <li>❖ the health crises in developing countries and LDCs are caused by pandemic and endemic third world diseases</li> <li>❖ new medicines for these diseases are not sought and developed; pharmaceutical companies focus on sophisticated diseases for R&amp;D costs to be recovered</li> <li>❖ if new medicines for these diseases, eg for HIV/AIDS, are found they are under patents which grant exclusive rights</li> <li>❖ this means that manufacturing and distribution rights are exclusive to the patent owner – are “monopolised”</li> <li>❖ the result is a pricing system making these medicines unaffordable and inaccessible to poor people</li> </ul> </li> </ul>

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<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<h2 style="text-align: center;">IP AND PUBLIC HEALTH: CHALLENGES AND ISSUES</h2> <ul style="list-style-type: none"> <li>■ 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"> <li>❖ patent rights are exclusionary and monopolistic</li> <li>❖ patent rights give rise to excessive drug prices</li> <li>❖ patent rights keep out cheaper generic substitutes</li> <li>❖ patent rights do not promote technology transfer</li> <li>❖ world-wide patent coverage hampers parallel importation</li> <li>❖ patent owners are unwilling to grant voluntary licences</li> <li>❖ pharmaceutical industry is not actively seeking cures for neglected diseases</li> </ul> </li> </ul>

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<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<h2 style="text-align: center;">IP AND PUBLIC HEALTH: CHALLENGES AND ISSUES</h2> <ul style="list-style-type: none"> <li>■ 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"> <li>❖ the majority, ie about 120, of the 151 WTO member states are developing and least-developed countries (LDCs); 41 are African countries</li> <li>❖ the majority of the 193 WHO member countries are developing countries and LDCs; 48 are African countries</li> <li>❖ the majority of the 182 WIPO member countries are developing countries and LDCs; 49 are African countries</li> <li>❖ developing countries have formed several negotiating blocks to present united positions to WTO/WHO/WIPO</li> <li>❖ clearly numerical weight is on the side of developing countries and LDCs; economic power and technology advancement on the side of the developed countries</li> </ul> </li> </ul>

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<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<h2 style="text-align: center;">IP AND PUBLIC HEALTH: CHALLENGES AND ISSUES</h2> <ul style="list-style-type: none"> <li>■ 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"> <li>❖ the poorest populations (one third of world population) which suffer two thirds of the world's disease burden</li> <li>❖ the governments in developing countries and LDCs, responsible for providing essential health care</li> <li>❖ pharma companies which invest heavily in R&amp;D and product development to provide new drugs</li> <li>❖ government agencies in developing countries and LDCs are big buyers of medicines and have negotiating power</li> <li>❖ the research institutions which have to seek and develop cures also for so-called neglected diseases</li> </ul> </li> <li>■ the challenge is to find solutions which will be effective, affordable, sustainable and legitimate</li> </ul>

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<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<h2 style="text-align: center;">SEARCH FOR SOLUTIONS: INITIATIVES BY WIPO</h2> <ul style="list-style-type: none"> <li>■ 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"> <li>❖ to make available to developing countries and LDCs, within the framework of the WTO/WIPO agreement, advice on the use of TRIPS flexibilities</li> <li>❖ to preserve and promote the benefits of a rich and accessible "public domain" of accessible information</li> <li>❖ to urge its Intergovernmental Committee (IGC) to accelerate the protection of genetic and biological resources and TK, including traditional medication</li> <li>❖ to facilitate and enhance cooperation and exchange of information by research and development institutions in developed and developing countries</li> <li>❖ to identify cooperation initiatives on IP-related matters with other UN agencies, including WHO and WTO</li> </ul> </li> </ul>

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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"> <li>■ WIPO provides a well-positioned international forum to identify needs relating to IP rights           <ul style="list-style-type: none"> <li>❖ the need for compulsory licences for non-working</li> <li>❖ the need to provide protection for indigenous biological resources and related TK</li> </ul> </li> <li>■ WIPO is prepared to cooperate with other players           <ul style="list-style-type: none"> <li>❖ WIPO is identified by CIPIH report of WHO for collaboration to promote patent pools of upstream technologies to address diseases disproportionately affecting developing countries</li> <li>❖ WIPO and WTO recognised that cooperation was desirable, concluded a collaboration agreement on IP</li> </ul> </li> </ul>

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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"> <li>■ 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"> <li>❖ 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</li> </ul> </li> <li>■ CIPIH report published in 2006; several recommendations relate to IP           <ul style="list-style-type: none"> <li>❖ recognises that the patent system has an incentive function and a disclosure function</li> <li>❖ research tools and platform technologies to be maximised, better use of universities and research bodies in health area</li> <li>❖ better use of patent pools, compulsory licensing mechanisms</li> <li>❖ recognises that developing countries have a rich source of medical traditional knowledge, and medical properties of plants</li> </ul> </li> </ul>



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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"> <li>■ following on the CIPIH report, the WHA in May 2006 passed resolution 59.24 recognising that             <ul style="list-style-type: none"> <li>❖ the world is facing a growing burden of diseases disproportionately affecting developing countries</li> <li>❖ safe and affordable new products to treat these diseases must be developed</li> <li>❖ advances in biomedical science to be harnessed</li> <li>❖ IP rights can be beneficial, offer incentives for research</li> <li>❖ member countries urged to make global health and access to medicines a priority</li> <li>❖ the Intergovernmental Working Group (IGWG) established; objective of preparing a global strategy and plan of action to implement the recommendations</li> </ul> </li> </ul>

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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"> <li>■ public health issues and access to medicines dominated the 2001 WTO Meeting in Doha, Qatar             <ul style="list-style-type: none"> <li>❖ the proceedings were characterised by serious confrontation between countries on the issue of the public health crisis</li> </ul> </li> <li>■ WTO Council issued the Doha Declaration on Public Health in 2001, recognising –             <ul style="list-style-type: none"> <li>❖ the gravity of public health problems (HIV/AIDS, TB, Malaria) afflicting developing and least-developed countries</li> <li>❖ IP protection is important for development of new medicines, to counterbalance the substantial R&amp;D investment</li> <li>❖ that there are concerns regarding the effect of IP protection on pricing of medicines</li> <li>❖ that TRIPS does not prevent member countries to protect public health and gain access to affordable medicines</li> <li>❖ that WTO/TRIPS initiative is part of a wider international action to address public health problems</li> </ul> </li> </ul>

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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"> <li>■ the Doha Declaration further confirmed           <ul style="list-style-type: none"> <li>❖ that member countries have the right to grant compulsory licences and to determine the grounds on which licences are granted</li> <li>❖ that member countries have the right to determine what constitutes a national emergency; public health crises can constitute a national emergency</li> <li>❖ that TRIPS leaves it to member countries to establish their own position on exhaustion of rights and legitimacy of parallel importation</li> <li>❖ that member countries without manufacturing capacity faced difficulty in using compulsory licensing</li> <li>❖ that TRIPS Council must find an expeditious solution by 2002 for a manufacturing licence system to provide cheaper medicines to developing countries and LDCs</li> </ul> </li> </ul>

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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"> <li>■ 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"> <li>❖ eligible importing country will grant a compulsory licence if product is patented in that country</li> <li>❖ exporting country will grant compulsory licence for manufacture and exportation</li> <li>❖ adequate remuneration to be paid for licence in exporting country; obligation to pay remuneration for licence waived for importing country</li> <li>❖ eligible importing country will provide measures to prevent re-exportation of product (except to LDCs or other developing countries in regional trade agreements)</li> <li>❖ TRIPS Council to be notified of licences granted and to monitor system</li> </ul> </li> </ul>

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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"> <li>■ early indications of extent of implementation of Doha licensing model into national laws <ul style="list-style-type: none"> <li>❖ implementing legislation has been enacted in Canada, Mexico, Norway</li> <li>❖ implementing legislation is in progress in EU, Indonesia, Korea, Sweden, Switzerland</li> <li>❖ implementing measures are being considered in Brazil, Bulgaria, France</li> <li>❖ SA has not yet passed legislation to implement the provisions of Art 31<i>bis</i></li> <li>❖ 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</li> </ul> </li> </ul>

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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"> <li>■ in the search for solutions to public health crises, the diversity of the issues must be acknowledged <ul style="list-style-type: none"> <li>❖ the flexibilities in TRIPS should be recognised, permitting countries to use measures to protect public health and to address national needs and emergencies</li> <li>❖ 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</li> <li>❖ effective healthcare structures should be established; many developing countries and LDCs lack adequate medicine distribution facilities even if they had access to those medicines</li> </ul> </li> <li>■ above all, to be effective the solution will have to be balanced, affordable, feasible – and should not be a disincentive to innovation</li> </ul>

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**Thank you for  
your attention  
Questions?**