

Adams & Adams
Intellectual Property Specialists



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CONTINUING EDUCATION
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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

COMMERCIALISATION

by
Bruce Lister
Adams & Adams

INTELLECTUAL PROPERTY RIGHTS AND
PHARMACEUTICAL PRODUCTS AND PROCEDURES

COMMERCIALISATION OF PROTECTED PRODUCTS

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COMMERCIALISATION

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- Taking protected product to market
- Bundle of IP rights
- Product may draw on variety of these rights
- Legislative environment broader than IP rights

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ROUTES TO COMMERCIALISATION

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- Direct sale
 - rights
 - products
- Licensing
 - inward licensing
 - outward licensing
 - cross licensing

	<h2 style="text-align: center;">DIRECT SALE</h2>
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<ul style="list-style-type: none">■ Valuation of product / IP■ Tax considerations■ Foreign Exchange considerations: Reg 10(1)(c)<ul style="list-style-type: none">❖ Couve v Reddot International■ Regulatory environment■ Competition Act

	<h2 style="text-align: center;">LICENSING</h2>
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<ul style="list-style-type: none">■ Compulsory licensing■ Agreement■ Granting of rights to do various things<ul style="list-style-type: none">❖ Rights vary according to IP■ Subject to matter of agreement■ Scope of rights

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

LICENSING (continued)

- Exclusive licence
- Sole licence
- Non-Exclusive

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

TERRITORIAL LIMITATIONS

- Agreement
- Statutory limitations
 - ❖ Patent Act
 - ❖ Trade Mark Act
 - ❖ Designs Act

	9 <h2 style="color: yellow;">ROLE OF TRIPS</h2>
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<ul style="list-style-type: none"> ■ TRIPS has build-in flexibilities which countries can use to structure their patent regimes to take into account their own needs and circumstances <ul style="list-style-type: none"> ❖ parallel importation and compulsory licences can be used to facilitate access to medicines – Art 6, 31 ❖ early working provision can accelerate market entry of generic substitutes – Art 30 ❖ government intervention is permitted; special measures can be adopted to provide for government use of patented products, eg in cases of national emergency or circumstances of urgency – Art 8 ■ Countries can use the appropriate combination of flexibilities to create a balanced solution

	10 <h2 style="color: yellow;">TRIPS PROVIDES FOR COMPULSORY LICENCES</h2>
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<ul style="list-style-type: none"> ■ TRIPS Art 31: member countries may allow use of the subject of a patent by government or third parties without authorisation of patent owner <ul style="list-style-type: none"> ❖ 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 <ul style="list-style-type: none"> ❖ 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

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">COMPULSORY LICENCES UNDER SOUTH AFRICAN PATENTS ACT, 1978</h2> <ul style="list-style-type: none"> ■ Patents Act, 1978 provides for patents for pharmaceutical inventions <ul style="list-style-type: none"> ❖ substance or composition for use in a method of treatment of human/animal body is patentable – s.25(12) ❖ use of substance or composition in a method of treatment of human/animal body is patentable – s.25(9) ❖ but excluded are: methods of treatment of the human/animal body – s.25(11) ❖ patent term: 20 years – s.46 ■ Provision for compulsory licences to third parties <ul style="list-style-type: none"> ❖ in case of abuse of patent rights – s.56 ❖ in case of dependent patents – s.55 ■ Provision for compulsory licence to State <ul style="list-style-type: none"> ❖ to be used for public purposes – s.4

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">COMPULSORY LICENCES UNDER PATENTS ACT, 1978</h2> <ul style="list-style-type: none"> ■ A compulsory licence may be granted on the ground of abuse of rights in case of – <ul style="list-style-type: none"> ❖ non-working of patented invention on a commercial scale and to adequate extent within time limits ❖ demand for the patented product not being met to adequate extent and on reasonable terms ❖ refusal of patentee to grant a licence on reasonable terms, and trade or industry in SA prejudiced and it is in public interest that licence be granted ❖ demand for patented product met by importation and price in SA excessive compared to price in other countries where patented product manufactured by patentee/licensee

	<p style="text-align: right;">13</p> <h2 style="text-align: center;">COMPULSORY LICENCES UNDER PATENTS ACT, 1978 (continued)</h2>
<p>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<ul style="list-style-type: none">■ Provisions wide enough to cover some cases of inaccessible medicines<ul style="list-style-type: none">❖ provisions substantially compliant with TRIPS Art 31❖ specific discretion to court to preclude importation■ Compulsory licence to be granted on basis of court procedure; only four cases decided to date<ul style="list-style-type: none">❖ courts not specifically required to define “excessive pricing” but considered pricing under “reasonable terms”❖ looked at cost to patentee for manufacture and marketing, the basis of negotiation with customers, whether trade can carry the price charged

	<p style="text-align: right;">14</p> <h2 style="text-align: center;">COMPULSORY LICENCES</h2>
<p>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<ul style="list-style-type: none">■ Use it or lose it■ Incentive to commercialise■ Be aware of abuse of commercialisation■ IP serves to stimulate creativity to benefit community

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">TRIPS PROVIDES FOR EXCEPTIONAL MEASURES</h2> <ul style="list-style-type: none"> ■ TRIPS Art 8.1: countries may adopt measures necessary to protect public health; such measures to be consistent with TRIPS <ul style="list-style-type: none"> ❖ no indication in TRIPS of how public health to be assessed or addressed, or of nature of measures permissible under this provision ■ TRIPS Art 8.2: countries may adopt appropriate measures to prevent abuse of IP rights by right owners; measures to be consistent with TRIPS <ul style="list-style-type: none"> ❖ no indication of what constitutes abuse of rights – perhaps excessive prices – or of nature of measures ❖ abuse of patent rights generally addressed by way of compulsory licences

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">MEASURES TO PROTECT PUBLIC HEALTH: SA MEDICINES ACT, 1965</h2> <ul style="list-style-type: none"> ■ In 1997 Medicines and Related Substances Amendment Act 90 of 1997 enacted, to amend Medicines Act, 1965 <ul style="list-style-type: none"> ❖ Intention a streamlined, non-judicial “licensing” procedure ■ S.15C empowers Minister (of Health) to prescribe conditions for supply of more affordable medicines to protect public health <ul style="list-style-type: none"> ❖ Minister may, notwithstanding anything in Patents Act, determine that patent rights for medicines shall not cover certain acts once medicine marketed by owner of medicine ❖ Minister may prescribe conditions for import of medicine by persons other than marketing registration holder, if medicine of identical composition and quality as registered medicine and originates from original site of manufacture ❖ Minister may prescribe registration procedure and use of medicine so imported

	17 <h2 style="margin: 0;">COURT PROCEEDINGS BY PMA AND OTHERS v STATE</h2>
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<ul style="list-style-type: none"> ■ In 1998 a High Court application was lodged by Pharmaceutical Manufacturers' Association and 39 pharmaceutical companies against the President of SA and others <ul style="list-style-type: none"> ❖ constitutionally of s.15C contested on basis that Minister could by administrative act override Patents Act ❖ PMA also contended that s.15C contrary to TRIPS Art 28 ❖ government relied on TRIPS Art 8: members may adopt measures to protect public health ■ Issues could be paraphrased: Is 20-year term for pharmaceutical patents legally justifiable? <ul style="list-style-type: none"> ❖ HIV/AIDS Treatment Action Campaign (TAC) intervened as amicus curiae with extensive lobbying

	18 <h2 style="margin: 0;">COURT PROCEEDINGS BY PMA AND OTHERS v STATE</h2>
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<ul style="list-style-type: none"> ■ In 2001 pharmaceutical companies withdrew the case on basis of an underlying settlement <ul style="list-style-type: none"> ❖ Government undertook <ul style="list-style-type: none"> ➢ to set up a working group with the pharma industry to implement s.15C ➢ to honour international obligations under TRIPS ❖ pharma industry recognised that <ul style="list-style-type: none"> ➢ Government may enact legislation and adopt measures to protect public health ➢ Government may broaden access to medicines in accordance with Constitution and TRIPS ■ Outcome and subsequent events show that this was a balanced solution, in interest of all parties

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LESSON

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- Strive for win-win
- Use commercialisation to meet needs
- Enjoy benefits of IP rights
- Be aware of economic/political environment and legal restrictions

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PARALLEL IMPORTATION

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- 'Parallel importation' is the importation into a country, without the authority of the patent owner, of a patented product released onto the market in another country by the patent owner / his licensee
 - ❖ based on the principle that once a patented product has been sold, the patentee's right has been exhausted
 - ❖ no consensus amongst countries whether exhaustion of rights should apply only nationally or internationally
 - ❖ if exhaustion applies internationally, parallel imports will not constitute infringement of patent rights
 - ❖ if exhaustion principle applies only nationally, parallel importation will constitute infringement unless local laws provide otherwise

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

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PARALLEL IMPORTATION (continued)

- TRIPS does not resolve issue of exhaustion of rights and legitimacy of parallel importation
 - ❖ Art 28.1 prescribes the exclusive rights to be conferred on patent owner, including importation right with a footnote referring to Art 6
 - ❖ Art 6 states that nothing in TRIPS shall be used to address the issue of exhaustion of IP rights
- It is therefore a matter for national laws to stipulate the domestic position as regards exhaustion and legitimacy of parallel importation
- In South Africa provision is made for parallel importation under Medicines Act, 1965

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

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PARALLEL IMPORTATION (continued)

- For importation of a product to qualify as parallel importation the product must be genuine product
 - ❖ importation of infringing product (eg generic substitute) will constitute infringement of patent right
 - ❖ where price differentials exist in different countries in price of genuine product, parallel importation from cheaper country could provide cost benefit
 - ❖ end user will derive benefit only if parallel importer passes cost benefit on to the end user
 - ❖ countries with inadequate manufacturing capacity could acquire patented product through parallel importation

	<p style="text-align: right;">23</p> <h2 style="text-align: center;">POSITION ON PARALLEL IMPORTATION IN SOUTH AFRICA</h2>
<p>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<ul style="list-style-type: none"> ■ Generally accepted that parallel importation of patented products is not permitted ■ Section 45(1) Patent Act – includes right to exclude others from importing invention ■ Section 45(2) does not indicate that international exhaustion will apply ■ <i>Stauffer Chemical Company v Agricura Ltd (1979) BP 168</i>: confirmed only national exhaustion applies

	<p style="text-align: right;">24</p> <h2 style="text-align: center;">POSITION ON PARALLEL IMPORTATION IN SOUTH AFRICA (continued)</h2>
<p>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<ul style="list-style-type: none"> ■ In May 2003, after consultation process with pharma companies, Government promulgated s.15C and implementing Regulations <ul style="list-style-type: none"> ❖ Reg 7 provides for parallel importation of a medicine on the basis of a permit issued by the Minister (of Health) ❖ a pre-condition for the grant of a permit is that the medicine is being sold outside South Africa with the consent of the patent owner ❖ medicine to be imported must have marketing approval in the country of export ❖ permit holder must apply for regulatory approval in SA

	<p style="text-align: right;">25</p> <h2 style="text-align: center;">POSITION ON PARALLEL IMPORTATION IN SOUTH AFRICA (continued)</h2>
<p>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<ul style="list-style-type: none"> ■ In June 2003 the Minister published guidelines for the parallel importation of medicines <ul style="list-style-type: none"> ❖ guidelines do not limit importation provisions to medicines required for public health emergencies ❖ no information available to date on permits granted ■ Need for importation of medicines resolved without necessity of reducing patent term <ul style="list-style-type: none"> ❖ solution also in line with TRIPS

	<p style="text-align: right;">26</p> <h2 style="text-align: center;">LIMITED EXCEPTION INTRODUCED BY SOUTH AFRICA</h2>
<p>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<ul style="list-style-type: none"> ■ In SA, section 69A of Patents Act introduced a Bolar-type provision <ul style="list-style-type: none"> ❖ provision not expressly limited to pharmaceutical products; no discrimination as to technology ❖ permits non-commercial use, exercise, disposal or importation of patented subject matter solely for the purpose of obtaining, developing and submitting information required for regulatory approval of product ❖ prohibits possession of patented subject matter for any other purpose (ie prohibits stockpiling) ■ Need for early availability of generic equivalents resolved without necessity to reduce patent term

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">TRIPS DOES NOT TOLERATE UNFAIR COMPETITION</h2> <ul style="list-style-type: none"> ■ TRIPS does not tolerate practices which restrain trade or are anti-competitive <ul style="list-style-type: none"> ❖ appropriate measures may be adopted to prevent or correct such practices ■ TRIPS Art 8.2: members may adopt measures to prevent practices unreasonably restraining trade <ul style="list-style-type: none"> ❖ no indication of practices which would cause restraint ■ TRIPS Art 31(k): compulsory licences may be allowed to remedy practices determined to be anti-competitive <ul style="list-style-type: none"> ❖ no indication given of practices which would be anti-competitive

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">INTERVENTION BY SOUTH AFRICAN COMPETITION COMMISSION</h2> <ul style="list-style-type: none"> ■ The South African 1998 Competition Act applies to all economic activity and can override the Patents Act <ul style="list-style-type: none"> ❖ contains specific provision for exemption in respect of practices that relate to exercise of IPRs – s.10(4) ❖ this does not assist patent owners who exercise a patent in a manner constituting abuse of a dominant position – s.8 ■ In 2003 the Treatment Action Campaign and others lodged a complaint against two pharma companies, alleging that by refusing to licence their patents on first-line ARVs the companies had <ul style="list-style-type: none"> ❖ engaged in excessive pricing – s.8(a) ❖ denied a competitor access to an essential facility – s.8(b) ❖ engaged in an exclusionary act – s.8(c)

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">INTERVENTION BY COMPETITION COMMISSION</h2> <ul style="list-style-type: none"> ■ Before the matter went to trial, the Competition Commission announced that settlement agreements were concluded <ul style="list-style-type: none"> ❖ one company agreed to issue four licences and the other three licences to generic manufacturers ❖ licences permitted manufacture in South Africa, importation into South Africa, and exportation to sub-Saharan African countries ❖ licences permitted licensees to combine the relevant ARV drug with other ARVs

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">INTERVENTION BY COMPETITION COMMISSION (continued)</h2> <ul style="list-style-type: none"> ■ Concerns were raised by pharma companies that all patentees were placed at risk: a patent gave the patentee 100% of the market and thus could place the patentee in a dominant position <ul style="list-style-type: none"> ❖ Commission stated that a product market definition depends not on the existence of patent but on the substitutability of a product with comparable products ❖ thus market definition depends on substitutability between different ARVs ■ Need for access to manufacture resolved without necessity of reducing patent term, and in TRIPS compliant manner

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">VOLUNTARY LICENCES AND DONOR PROGRAMMES</h2> <ul style="list-style-type: none"> ■ After the withdrawal of the court case in 2001 the pharma industry launched many positive initiatives <ul style="list-style-type: none"> ❖ grant of voluntary licences to SA's leading generic manufacturer for the first-line ARVs, AZT, 3TC, stavudine, didanosine, nevirapine and efavirenz ❖ technology transfer to SA's leading generic manufacturer for essential antibiotics capreomycin and cycloserine for treatment of drug-resistant tuberculoses ❖ donation of diflucan (for life-threatening infections to countries with high HIV prevalence) with training of healthcare providers ❖ supply of malaria medication at cost to public sector patients ❖ free supply of leprosy medication to patients in public sector ■ This is in line with the principle of voluntary or "out-licensing" rather than relying on law reform

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">STATE PURCHASE/IMPORTATION</h2> <ul style="list-style-type: none"> ■ Regulation 3 provides for international tendering procedure ■ To enable State to obtain medicine internationally if lower price or essential for national health ■ Unclear whether limited to authentic medicines under Patents or whether generics also included.

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**Thank you for
your attention
Questions?**