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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

BIOLOGICS

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INTELLECTUAL PROPERTY RIGHTS AND
PHARMACEUTICAL PRODUCTS AND PROCEDURES

CONCEPT OF BIOLOGICS

	<h2 style="color: yellow;">OVERVIEW</h2>
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<ul style="list-style-type: none"> ■ definition and content ■ relevance of biological research ■ rules governing bioprospecting ■ interface with IP ■ non-patent protected formulations ■ traditional remedies

	<h2 style="color: yellow;">DEFINITION AND CONTENT</h2> <p style="color: yellow;">CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) - FDA</p>
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<ul style="list-style-type: none"> ■ Biologics include a wide range of medicinal products such as <u>antibodies, vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins</u> ■ Biologics can be composed of <u>sugars, proteins, or nucleic acids</u> or <u>complex combinations of these substances</u>, or may be <u>living entities such as cells and tissues</u> ■ Biologics are isolated from a variety of <u>natural sources</u> - <u>human, animal, or microorganism</u> - and may be produced by <u>biotechnology methods</u> and other technologies ■ <u>Gene-based and cellular biologics</u>, for example, often are at the <u>forefront of biomedical research</u>, and may be used to treat a variety of medical conditions for which no other treatments are available

	DEFINITION AND CONTENT (CONT, SELECTED CATEGORIES OF BIOLOGIC AGENT STRUCTURE (MARROW, 2004)
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<ul style="list-style-type: none"> ■ Hormone (growth hormone, parathyroid hormone, insulin): A substance, usually a peptide or steroid, produced by one tissue and conveyed by the bloodstream to another to effect physiological activity, such as growth or metabolism. ■ Interferons: Proteins that are normally produced by cells in response to viral infection and other stimuli. ■ Interleukins: A large group of cytokine proteins. Most are involved in directing other immune cells to divide and differentiate. ■ Growth factor: A substance such as a vitamin B12 or an interleukin that promotes growth, especially cellular growth. ■ Monoclonal antibodies (MAbs): A single species of immunoglobulin molecules produced by culturing a single clone of a hybridoma cell. MAbs recognize only one chemical structure, i.e., they are directed against a single epitope of the antigenic substance used to raise the antibody.

	DEFINITION AND CONTENT (CONT, SELECTED CATEGORIES OF BIOLOGIC AGENT STRUCTURE (MARROW, 2004)
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<ul style="list-style-type: none"> ■ Polypeptides: Peptides containing ten or more amino acids. Typically, a peptide consists of fewer than 50 amino acids, while a protein has more than 50 amino acids. ■ Proteins: Naturally occurring and synthetic polypeptides having molecular weights greater than about 10,000 (the limit is not precise). ■ Vaccine: An agent containing antigens produced from killed, attenuated or live pathogenic microorganisms, synthetic peptides, or by recombinant organisms. Used for stimulating the immune system of the recipient to produce specific antibodies providing active immunity and/or passive immunity in the progeny.

	<p>7</p> <h2 style="text-align: center;">MOST ACCEPTED DEFINITION</h2>
<p>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<p>Biologics are created by either microorganisms or mammalian cells and are large complex molecules most of which are protein or polypeptides.</p> <p>Origin; shape and structure; type of molecules.</p> <p>All these factors inform the method of production, analysis, formulation, storage application etc = high cost of biologics</p>

	<p>8</p> <h2 style="text-align: center;">RELEVANCE OF BIOLOGICAL RESEARCH</h2>
<p>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<p>The growth of genomics and proteomics and the pharmaceutical products that inevitably will be developed will change the lives of every person in the United States and perhaps, the world.</p> <p style="text-align: center;">THOMAS MORROW, MD</p> <p>Genomics is the study of the genomes of organisms. The field includes intensive efforts to determine the entire DNA sequence of organisms and fine-scale genetic mapping efforts.</p> <p>Proteomics/Proteomics is the large-scale study of proteins, particularly their structures and functions and interactions</p>

	<p style="text-align: right;">9</p> <h2 style="text-align: center;">RELEVANCE OF BIOLOGICAL RESEARCH EXAMPLE: STEPS IN THE DEVELOPMENT OF MOST BIOLOGICS</h2>
<p>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<ul style="list-style-type: none"> ■ Bioinformatic analysis ■ Isolating the gene of interest, could include gene modification ■ Gene cloning and the production the protein encoded by the gene of interest ■ Conducting bench-experiments to determine the role of the protein the disease ■ Developing potential remedies ■ Bioassays

	<p style="text-align: right;">10</p> <h2 style="text-align: center;">BIOPROSPECTING BIOPROSPECTING ACT AND REGULATIONS</h2>
<p>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<ul style="list-style-type: none"> ■ What is bioprospecting? In relation to indigenous biological resource means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation... ■ Need a bioprospecting permit ■ Access and benefit-sharing: Issue of a permit may require the applicant to conclude a MTA and/or a BSA with the person(s) who gives access to the biological resource or knowledge relating to the biological resource wherein such knowledge leads to the initiation or contributes the development of product or service.

	11
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">SOUTH AFRICAN PATENT AMENDMENT ACT 20 OF 2005</h2> <ul style="list-style-type: none"> ■ Complements the Biodiversity Act ■ Every applicant who lodges an application for a patent accompanied by a complete specification shall lodge with the registrar a statement in the prescribed Patent Form P.26, stating whether or not the invention is— <ul style="list-style-type: none"> (i) directly derived from an indigenous biological resource or a genetic resource; and (i) based on or derived from traditional knowledge or traditional use.

	12
INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<h2 style="text-align: center;">IP – PATENT APPLICATIONS/PATENTS</h2> <ul style="list-style-type: none"> ■ Bioinformatics: sequence data per se is not patentable ■ What is important? <ul style="list-style-type: none"> eg protein/polypeptide? nucleic acids encoding the protein/polypeptide? expression cassettes/vectors? medical use of protein/polypeptide, nucleic acid etc method of manufacture?

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<p style="text-align: right;">13</p> <h2 style="text-align: center;">NON-PATENT PROTECTED FORMULATIONS 'FOLLOW-ON BIOLOGICS'</h2>
	<ul style="list-style-type: none"> ■ Follow-on biologics vs generics drugs ■ Key principle for the regulation of follow-up biologics (from the Biotech Industry Organisation): <ul style="list-style-type: none"> ❖ Patient safety ❖ Scientific differences between drugs and biologics ❖ Maintain Patient-Physician relationship ❖ Preserve incentives for innovation

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES	<p style="text-align: right;">14</p> <h2 style="text-align: center;">CONCLUSIONS</h2>
	<ul style="list-style-type: none"> ■ Biologics are pharmaceutical embodiments of biotechnology. They are generally peptides and proteins, particularly monoclonal antibodies, but may include vaccines; ■ Currently over 150 approved biologics in the USA; ■ Growth of biologics is fueled by the growth of biological research, particularly bioinformatics, genomics and proteinomics; ■ May have to comply with bioprospecting regulations; ■ Special needs to protect IP but within existing IP regimes; and ■ Consider the current debate on the regulation of follow-on biologics

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**Thank you for
your attention
Questions?**