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WORLD INTELLECTUAL PROPERTY ORGANIZATION

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

WIPO-UPOV SYMPOSIUM ON INTELLECTUAL PROPERTY RIGHTS IN PLANT BIOTECHNOLOGY

organized by
the World Intellectual Property Organization (WIPO)

and
the International Union for the Protection of New Varieties of Plants (UPOV)

Geneva, October 24, 2003

BIOTECHNOLOGY PATENT OVERVIEW

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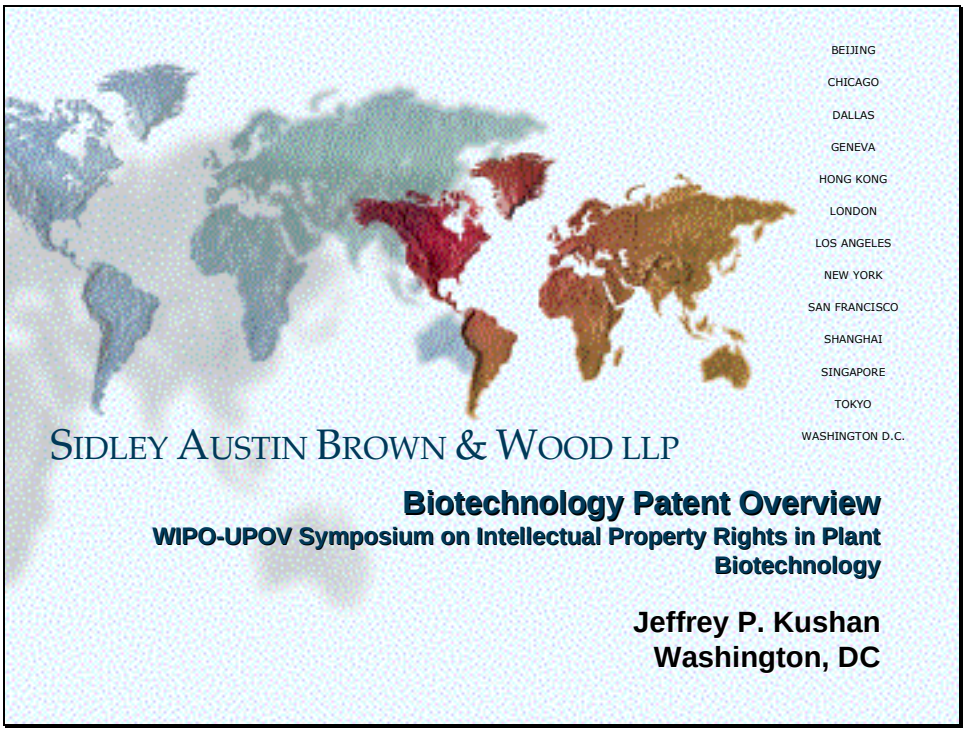
Slide 1



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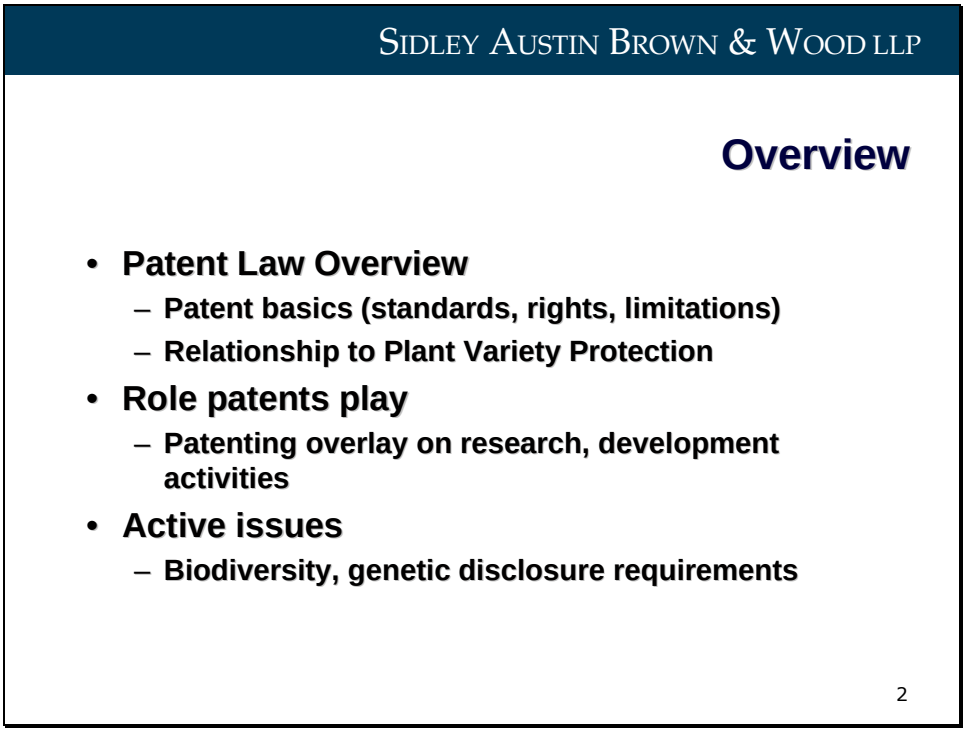

Slide 3

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Patent Basics
Patent Requirements - Novelty

- **Invention must be <u>novel</u> (new) over the prior art**
  - **Novelty**
    - The claimed invention has not been disclosed in the "prior art" (before the filing of the patent application)
    - Identity between claimed invention and subject matter in prior art is required
  - **Prior art**
    - Publicly accessible information captured in a form that can be found by scientists in the field
    - Information must be publicly accessible and the date of its disclosure must be able to be proven

3

Slide 4

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Patent Basics
Patent Requirements – Inventive Step

- **Invention must be <u>nonobvious</u> / involve an inventive step**
  - **Obviousness measures the difference between what is in the prior art and what is claimed**
    - The prior art must not suggest what is claimed as the invention
  - **Critical inquiry is the <u>claimed</u> invention relative to the prior art**
    - Knowledge that some unidentified substance exists in a plant extract does not mean that an isolated, purified and characterized chemical compound is "obvious"

4

Slide 5

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Patent Basics
Patent Requirements - Utility

- **Invention must be "<u>useful</u>" / industrially applicable**
  - **U.S. uses a more general standard**
    - Invention must have "practical utility" (real world use) or application in any field or industry, including agriculture
  - **EPC**
    - Articulates broad eligibility but then identifies certain types of inventions that do not have an industrial application
  - **Both standards differentiate abstract ideas, laws of nature, unapplied concepts from patentable inventions**

5

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Patent Basics
Eligibility –Utility Requirements

- **U.S. utility requirement articulated in USPTO utility examination guidelines -- invention must has specific, substantial and credible utility**
  - **Specific** = the utility of the invention must relate to the specific compound claimed, not the class of compounds to which the compound belongs
  - **Substantial** = the utility claimed for the invention must not be inconsequential to the claimed invention (e.g., use of sophisticated bioactive protein as an amino acid source)
  - **Credible** = the utility of the invention has a well-founded scientific basis
- **These standards are reflected in EPC decision of *Icos v. SmithKline* (OJ EPO 2002, 263)**

6

Slide 7

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Patent Basics
Patent Requirements - Disclosure

- **Disclosure requirements**
  - **The "quid pro quo" of the patent system – early disclosure of technical information for exclusive rights**
  - **Purpose of disclosure requirements is to put the public in possession of the invention once patent expires**

7

Slide 8

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Patent Basics
Patent Requirements - Disclosure

- **Main U.S. requirements**
  - **Enablement –** requires that the disclosure enable a person of ordinary skill to reproduce and make the invention
  - **Written description –** the patent application viewed as evidence of what the inventor "invented" as of the filing date
  - **Best mode –** what did the applicant believe to be the best mode of practicing if the invention – if any – at the time the application was filed
  - **Subjective best mode –** best mode is not objective, but subjective - what the patent applicant actually believed at the time the application was filed

8

Slide 9

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Patent Basics
Patent Requirements – Written Description

- **Disclosure Requirements (cont'd)**
  - ***Written description* requirement subject of extensive PTO and judicial developments**
    - **What must be established to support genus claim**
      - Claim to genus of functionally related compounds can be supported by identification of either representative number of species, or identification of structure-function relationship
      - Must consider predictability in the the field of the genus
    - **EST claims not usually sufficient to establish written description for the full length gene**
      - Critical inquiry is knowledge of the function of the gene, particularly where there is a substantial degree of variability for members of a family of related genes with conserved domains

9

Slide 10

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Patent Basics
Patent Requirements - Enablement

- **Disclosure requirements (cont'd)**
  - **Enablement law relatively settled in US**
    - **Patent specification must enable person of skill to practice the patented invention**
      - Wands factors (i.e., *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)) include (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the level of one of ordinary skill, (5) the level of predictability in the art, (6) the amount of direction provided by the inventor, (7) the existence of working examples, and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.
    - **Deposits played significant role at dawn of biotech industry, now less critical for enablement, but now used to support written description**

10

Slide 11

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Patent Basics
Patent Requirements – TRIPS Disclosure

- **Disclosure requirements (cont'd)**
  - **TRIPS Article 29 - Members can require disclosure of invention only to the degree necessary to "permit the invention to be carried out by a person skilled in the art"**
    - Members *optionally* can require disclosure of "best mode" if one is known to the applicant at time of filing of application
  - **Purpose to ensure that standards are consistently applied in all WTO Members**
    - Members cannot impose additional special disclosure requirements

11

Slide 12

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Patent Basics
Eligibility in the US

- **U.S. standard most "inclusive" as to eligibility**
  - **Any invention "made by the hand of man" is eligible to be patented**
    - Eligible does not mean it will be granted a patent – invention must be new, useful, nonobvious, adequately disclosed and described
  - ***Diamond v. Chakrabarty*, 100 S.Ct. 2204 (1980)**
    - "A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability and the inventions most benefiting mankind are those that "push back the frontiers of chemistry, physics, and the like."
    - "Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable."

12

Slide 13

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Patent Basics
Eligibility - TRIPS

- **TRIPS Article 27.1 mandates eligibility for all inventions that are novel, involve inventive step, and are industrially applicable**
- **Articles 27.2, 27.3 then define permissible optional exceptions Members may make to the general rule**
  - Critical perspective for interpretation – everything is to be eligible to be patented unless there is a specifically defined exception authorized by the Agreement

13

Slide 14

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Patent Basics
Eligibility – 27.2 Exclusions

- **Article 27.2 exclusion:**
  - **Permits Members to exclude patents on inventions that may not be used in their territory because the invention presents serious threats to "*ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment"**
    - Members cannot deny patents under Article 27.2 but allow parties to use the technology in their territory

14

Slide 15

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Patent Basics
Eligibility – 27.3(a) Exclusions

- **Article 27.3(a) exclusion**
  - **Permits Members to exclude patents on process inventions (i.e., therapeutic, surgical or diagnostic methods performed on the human or animal body)**
    - Based on EPC Article 53(c)
  - **Does not allow Members to limit eligibility for product claims (e.g., compounds or compositions to be used in therapy, diagnosis or surgical methods)**

15

Slide 16

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Patent Basics
Eligibility – 27.3(b) Exclusion

- **Article 27.3(b)**
  - **Permits members to exclude plant and animal inventions (i.e., products) or essentially biological processes**
  - **Patents must be made available for**
    - **Microorganisms**
      - Bacteria, yeast, fungi
      - Cell lines (e.g., hybridomas, transformed cell lines)
    - **Processes that are not essentially biological (e.g., manipulation of particular cellular function to produce desired result)**
    - **Definition of "essentially biological"**

16

Slide 17

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Patent Basics
Eligibility – 27.3(b) Plant Variety Protection

- **Article 27.3(b) (cont'd)**
  - **Also imposes conditional requirement – if patents not granted on plant inventions, Member must make available effective *sui generis* protection for plant varieties**
  - **Effective must be construed in light of purpose of protection**
    - Gives exclusive rights in the plant variety
    - Look to UPOV as standard recognized as establishing effective standards for protection

17

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Patent Basics
Eligibility – Gene Patents

- **Patents on "genes"**
  - **Gene is a sequence of nucleotides that encodes a polypeptide**
    - "Naturally" occurring gene is found as a non-contiguous sequence of nucleotides in a chromosome
    - Research identifies the parts of the sequence that encode the polypeptide
- **Patent gives rights in a chemical compound made using this information**
  - **A new, non-naturally occurring nucleotide sequence that excludes non-coding nucleotides found in the naturally-occurring sequence**

18

Slide 19

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Patent Basics
Eligibility – US/EPC Developments

- **US/EPC law requires identification of the complete coding sequence and the function/role played by the gene or its expression product**
  - Patents not granted on sequences lacking a characterized function
  - EU Biotech Directive Recital 23 ("Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention")

19

Slide 20

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Patent Basics
Eligibility – Natural v. Non-Natural

- **Naturally occurring materials**
  - Patent law draws line between "naturally occurring" materials and inventions made through human intervention
  - Patent rights cannot give exclusive rights in living organism in the form it is found in nature (i.e., unchanged by human intervention)
- **Non-naturally occurring inventions**
  - Genetically transformed plant or animal
    - Made by "genetic engineering" or through other techniques
  - Chemical compounds or compositions isolated from plant, animal or microorganism
  - Composition of purified, cultured, stable microorganism

20

Slide 21

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Patent Basics
Rights Conferred

- **Patents confer exclusive rights**
  - **Right to prevent others from making, using, selling, offering for sale or importing invention without authorization**
  - **Patents convey much information, but give rights only as defined in the claims.**
    - Claims define the "invention" that is found to be patentable

21

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Patent Basics
Limitations on Patent Rights

- **Most countries limit ability of patent owner to enforce rights in certain circumstances**
  - **Experimental use of the invention –** to investigate and evaluate the invention to determine how it works
  - **U.S. unusual** – no statutory research exception, some freedom left to conduct purely non-commercial research using patented invention

22

Slide 23

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Patent Basics
Limitations on Patent Rights

- **Practical limitations**
  - **Not efficient, practical or conducive to product development efforts for patent owners to aggressively enforce patents whenever possible**
    - Common to permit use of patented technology by universities and other research-focused organizations to facilitate development of the technology
  - **Real world experience shows that patent litigation rare relative to patent licensing activities**

23

Slide 24

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Patent versus Plant Variety Protection Requirements

Patent	Plant Variety Protection
Novel Useful/Industrially applicable Non-obvious/inventive step Adequately described in the application	Novel Stable Distinct Uniform Application to be filed but not substantive

24

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Patent versus Plant Variety Protection Rights Conferred

Patent	Plant Variety Protection
Prevent unauthorized making, using, selling, offering for sale or importing of patented invention	Prevent production or reproduction (multiplication), conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing, stocking for any of these purposes
Rights exist with respect to what is defined by the claims of the patent	Rights in propagating material, in harvested material and products derived from the harvested material

25

Slide 26

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Patent versus Plant Variety Protection Exceptions

Patent	Plant Variety Protection
TRIPS Article 30 – uses that do not unreasonably conflict with the legitimate rights of the patent owner, taking into account those of third parties *Generally* – experimental use that does not have clear commercial implication	Mandatory exceptions permit use of propagating material for (i) private, non-commercial use, (ii) research on the protected variety, (iii) to produce a new variety. Optional exception to permit farmers to use harvested material from their plantings for future planting on their holdings.

26

Slide 27

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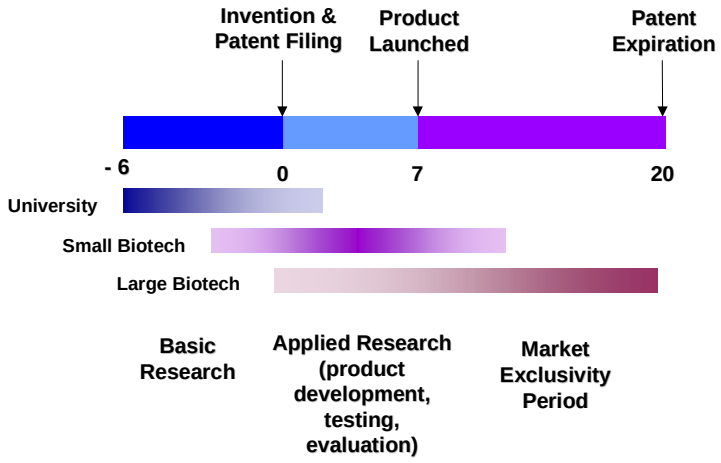
Practical Considerations on Patent Use



27

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Role of Patents in R&D

- **Role of patent exclusivity**
  - **Patents enable members of a research and development team to ensure that the "output" of the effort (e.g., a new product or service) cannot be used without authorization**
    - **Prevents "free riding" on the investments made by the team by preventing unauthorized use of what is patented**
    - **Enables the team to (a) receive a fair return on their investment, and (b) ensure that the patented technology is effectively exploited by delivering new products and services to the market**

28

Slide 29

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Role of Patents in Product Development

- **Patent rights can be licensed in the manner that best promotes commercial exploitation of the invention**
  - **Field-limited exclusive licenses – exclusive licenses within defined fields of use**
    - License conveys exclusive use of patented gene in specific crops for one entity, and to other crops for another entity
  - **Non-exclusive licensing limited by scope of license**
    - Right to incorporate/use gene in specific varieties, and to sell specific varieties on non-exclusive basis

29

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Active Issues
Special Disclosure Requirement (SDR) Proposals

- **Genetic resource disclosure requirements**
  - Proposals to require – in addition to patent-relevant disclosure – special disclosure requirements for determination and disclosure of origin/source of "genetic resources" (anything having DNA)
  - Purposes ostensibly to ensure compliance with benefit sharing obligations of the Convention on Biological Diversity or individual countries
  - All concepts envision penalty of refusal of patent grants, or loss of patent rights

30

Slide 31

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Active Issues
SDR Concerns

- **Scope of proposals is unrelated to the objectives of the CBD**
  - Few patentable inventions arise from screening of undeveloped "genetic resources" (e.g., undeveloped germplasm samples)
  - Every biotech application mentions "genetic resources" but only a tiny fraction might concern genetic resources collected through bioprospecting activities covered by the CBD
  - Immense compliance burden and risks for system that, *by definition*, will not address the vast majority of bioprospecting activities

31

Slide 32

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Active Issues
SDR Concerns

- **Incentives for use of genetic resources are needed – special disclosure requirements being proposed will have the *opposite* effect!**
  - Very few incentives exist now for biotech companies to invest in research and development of undeveloped "genetic resources"
    - Immense cost and effort required with little prospect for commercially successful results
  - Attaching possible risks to patents on inventions made from use genetic resources creates an additional strong *disincentive* to develop products using such materials

32

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Active Issues
SDR Concerns

- **Proposals attempt to impose unfair and inappropriate burdens on <u>all</u> patent applicants**
  - Disclosure of origin would require research and analysis to produce results that are, by definition, unclear
    - Genetic lineage of a sample may reveal multiple "origins"
    - Origin at what date
    - What degree of relationship
  - Time pressures on filing applications are immense – proposed requirements would involve unworkable delays
- **Patent system is not the appropriate means to enforce CBD provisions**
  - If you don't pay taxes, you don't lose patent rights!

33

Slide 34

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Active Issues
SDR Conclusions

- **Regulate bioprospecting directly through laws/practices based on the CBD**
  - Creating uncertainty in validity of patents will eliminate commercial interest in R&D on genetic resources
  - Inappropriate to attempt to regulate this behavior using the patent system – both overbroad and ineffective
  - Presumes innovators are acting outside CBD-based regimes – no basis for this claim
  - Would introduce unworkable provisions into patent standards due to immense uncertainty as to the nature of the requirements for disclosure

34

Slide 35

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Questions?

- **Please send questions to:**

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35

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