

Propiedad Intelectual con foco en Patentes, Tecnología & Negocios
Intellectual Property focused on Patents, Technology & Business



Strategies for Protecting Biotech Inventions

Andrés Giallombardo—Alicia G. Alvarez,
Bottlenecks in the Establishment of Biotech-Based Companies
Instituto Leloir, October 5th-7th, 2011.

Propiedad Intelectual con foco en Patentes, Tecnología & Negocios

Intellectual Property focused on Patents, Technology & Business



I. A primer on Patents

Patents

● ¿What is a patent?

- An official document conferring ownership of an invention.
- Grants exclusive rights.
- Territorial scope.
- Limited in time.

EPO/PCT

- There are no “international patents”.
- Patents have national scope.
- Some supra-national organizations exist.

Patents

● ¿What is an invention?

- New Solution to a technical problem, of practical use in the industry.
- Are usually the result of methodical research
- Involve large sums of money invested in R+D

Why are Patents Granted?

In exchange for the granting of a patent, the inventor must disclose how to carry out the invention and use it.

Requirements

- New
- Inventive
- Industrial application

Patent Documents

- ❖ **Official forms/Bibliographic data**
- ❖ **Technical documents**
 - Abstract
 - Description and drawings (plus list of sequences in Biotech)
 - Claims

Description of the Invention

● Purposes:

- Disclose the invention in order to allow:
 - its repeatability by a skilled person in the art
 - examination by the Patent Office

- Allow the recovery of the technical information contained:
 - standardized structure

Description of the Invention

- **Technical field**
- **State of the art**
- **Definiton of the technical problem to be solved**
- **Proposed solution**

Description of the Invention

- **Complete and detailed description of the invention.**
- **Unexpected effects, advantages or properties.**
- **Industrial application of the invention.**

Claims

- Define the extension of the right.
- Must be clear, concise and self-supporting
- Description and drawings are only auxiliary
- Must be supported by the description
- Some degree of generalization is acceptable

Claims

Standardized wording

- N° of claim
- Preamble
- Transition
- Characterization

- **Scope of protection**

Given by the whole claim

Kinds of Inventions in Biotechnology

medicines

transgenic mice

Diagnostic

GLOWING CATS

DNA

treatment

ELISA

Oil Eating Bacteria

genes

Dolly

transgenic soybean

transgenic microorganisms

Proteins

CHIMERIC GENES

Vectors

Kinds of Inventions in Biotechnology

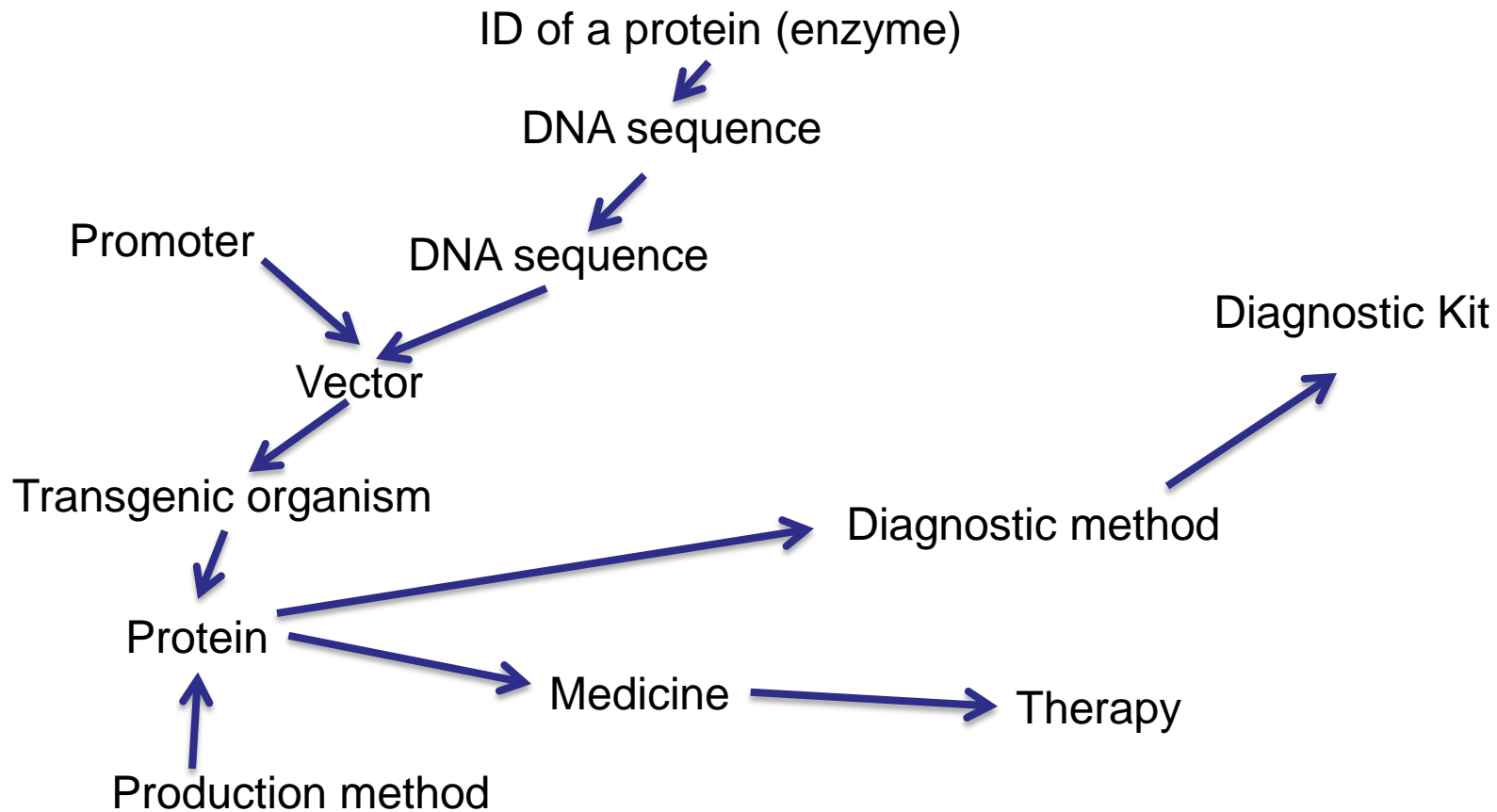
Products:

- DNA/RNA
- Proteins
- Vectors
- Microorganisms
- Medicines
- Diagnostic Kits

Procedures:

- Transformation methods
- Production methods
- Diagnostic methods
- Therapeutic methods

Typical developments in Biotech inventions



Exclusions of patentability

- Discoveries
- Human body or its parts (how small?)
- Animals
- Plants
- Essentially biological processes
- Diagnostic methods applied to humans or animals
- Therapeutic methods

Exclusion of Discoveries: substances pre-existing in nature

Do isolation and purification of DNA make it different
from what exists in nature?

Diagnostic methods

- The ones excluded are those applied to the human/animal body.
- Other methods are patentable (i.e. in vitro methods)

Treatment methods

- Almost universal exclusion
- Even if performed outside the body of the patient
- Important to differentiate between cosmetic and therapeutic (not always easy)

Essentially biological processes Microbiological process (vs. Traditional crossing/selection)

Microbiological process vs. traditional crossing/selection

Transgenics vs. Hybrids

Transgenic organisms

- Animals
- Plants (UPOV)
- Microorganisms (often treated as compounds)

Microorganisms:

- Non-transgenic microorganisms
- Convention on Biological Diversity
- Royalties!

Microorganisms:

- Sufficiency of disclosure
- Repeatability
- Deposit as an alternative/requirement

Budapest Treaty

- Recognition of a single deposit
- Designed institutions
- Argentina is not signatory, but...

II. Strategies for Patenting

Strategies for protecting Biotech inventions

- First, identify any potential conflict with previous employer
- Second, decide what to keep secret and what to patent
- Then, decide when/where to patent

When to file a patent application?

- Good quality document
- Publication of papers
- Grace period
- First to file vs. Sufficiency of disclosure.

What to include in the application?

- Compromise between disclosure and secret.
- Compromise between detail and number of claims.

Where to file a patent application?

- Identify Technology requirements
- Potential Markets
- Production countries

Where to file first?

- Paris convention (priority)
- Filing in Argentina:
 - No study before 12 months.
 - Additional applications.

Where to file first?

- If not strong search has been done > EPO
 - Search report in about 8 months if no priority
 - High quality reports
 - More expensive

Where to file first?

- If in a rush > USPTO provisional application
 - Few formalities
 - Will not be published
 - Matter can be added in the definitive
 - Can be used as priority
 - Relatively unexpensive

Where to file first?

- If we need time and broad protection > PCT
 - Priority can be claimed
 - Gives more time for decisions and finding investors
 - Search report published after 6 months with a written opinion
 - Entry on national phase about 30 months after initial filing
 - Must be a national or resident of a PCT member country

Propiedad Intelectual con foco en Patentes, Tecnología & Negocios

Intellectual Property focused on Patents, Technology & Business



III. Developing an IP Strategy

Traditional role of IP

- Part of the legal department
- Conduct prior art searches, drafting and prosecution
- Basic licensing and litigation
- Relationship with outside counsel

New role of IP

- Direct source of company value
- Essential tool in the development of business strategies
- Today, developing countries consider IP essential to development

Now, IP equals Patents

- Not many years ago patents were “industrial property”
- Trademark and Copyrights were referred to as
Intellectual Property
 - TM strategic form of marketing rather than licensing

Big companies have learnt how to manage the IP portfolio

- What to protect as the crown jewels
- What to license out
- What to give away

Small companies and start ups still fail to define a strategy on acquisition of rights

- Do not prevent disclosure of patentable inventions
- Do not properly document ownership of IP
- Do not implement a commercialization strategy

What to do to implement an IP strategy?

- Identify your business goals
- Collect IP business issues
 - Discussion with business, marketing, technical and legal personnel
- Build an IP culture

Developing an IP culture

- Employees must sign agreements on:
 - Property of information
 - Protection of the Proprietary and confidential information

Developing an IP culture

- Provide Employees with Confidential disclosure agreements to be used
 - When exchanging confidential information with third parties
 - When receiving confidential information from third parties
 - When disclosing confidential information to third parties

Developing an IP culture

- Develop and enforce a written procedure to record all potentially patentable activities
- Let the people know the importance of these procedures
- IP must be at the core of the development of business strategies

Propiedad Intelectual con foco en Patentes, Tecnología & Negocios
Intellectual Property focused on Patents, Technology & Business



Thank you very much!

Andrés Giallombardo—Alicia G. Alvarez,
Bottlenecks in the Establishment of Biotech-Based Companies
Instituto Leloir, October 5th-7th, 2011.