

E.S.A.BIO (Ecole Supérieure d'applications des biotechnologies) is pleased to invite you to an European intensive seminar, under the sponsorship of CANCA (Communauté d'Aménagement de Nice Côte d'Azur)¹ and with the collaboration of Ernest Gutmann and Dominique Guerre, European patent attorneys.

Management of industrial property rights in biotech : Sharing experiences.

This intensive seminar is designed for executives and other delegates seeking to use intellectual property rights to optimise the profitability of the innovative efforts taking place in their companies or academic institutions in the life science field and related areas. It aims at providing a discussion forum for the participants with experienced lecturers in the field of intellectual property and also with company and institution managers deeply involved in technology exchanges and IPR management.

19 – 23 January 2004, Nice (France)

**CUM
Centre Universitaire Méditerranéen
65 Promenade des Anglais
06000 NICE - FRANCE**

LECTURERS :

- **Jacques BARTHOLEYNS**, Executive director, strategy and intellectual property IDM (Immuno Designed Molecules) Paris.
- **Jo BURY**, General director of VIB (Flanders Interuniversity Institute for Biotechnology), Gent Belgium.
- **Giampiero DE LUCA**, Chief Intellectual Property Counsel and Member of the Executive Management Board, Serono International S.A., Geneva, Suisse.
- **Anne DESAIX**, French & European patent attorney, Ernest Gutmann Yves Plasseraud SA, Paris.
- **Jean-Luc GAL**, Seconded National Expert, European Commission - Directorate General Internal Market – Industrial Property, Brussels.
- **Ernest GUTMANN**, French & European patent attorney, Co-founder of Ernest Gutmann Yves Plasseraud SA, Paris.
- **Eric LE FORESTIER**, French & European patent attorney; Cabinet Regimbeau, Paris.
- **René ROYON**, Licensing consultant - Secretary general of CIOPORA, Mougins, France.
- **Maître Pierre VERON**, Industrial property lawyer, Véron et associés, President of EPLA (European Patent Lawyers Association), Paris.
- **Jacques WARCOIN**, French & European patent attorney; Cabinet Regimbeau, Paris.
- **Marc ZABEAU**, Professor, Scientific adviser , Department of Plant Systems Biology, VIB / Gent University,. Director of Methexis Genomics, Belgium.

¹ Community for the development of the Nice Côte d'Azur Region

Monday 19 January 2004

WELCOME

09.00 ~ 09.10 Pr Bernard ASSO, Vice President CANCA, Deputy Mayor of Nice, Vice President Region of Alpes Maritimes, Professor of Law University of Nice.

OPENING REMARKS

09.10 ~ 09.20 Jean-Michel NICOLAÏ, Directeur General of E.S.A.BIO., Paris.
René ZALISZ, Scientific director of E.S.A.BIO., Paris.

INTRODUCTION

09.20 ~ 09.30 Pr Moncef GUENOUNOU, President of E.S.A.BIO., Paris.

A - THE MAIN INDUSTRIAL PROPERTY SYSTEMS FOR THE PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

09.30 ~ 10.30 Mr. Ernest GUTMANN, European patent attorney, Ernest Gutmann-Yves Plasseraud S.A., Paris.

I - Patents : The biotechnological invention as a subject of a patent :

- The technical specifics of the (patentable) biotechnological invention and its features in common with a biochemical invention ;
- the nature and limits, as a general rule, of the rights conferred by the patent to its owner ;
- the patent *versus* ethics issue.

11.00 ~ 12.30

and 14.00 ~ 16.00 Mr. Jean-Luc GAL, Seconded National Expert, European Commission – Directorate General Internal Market – Industrial Property, Brussels.

Patents : The 98/44/EC directive and other legislation on the legal protection of biotechnological inventions:

a) The 98/44/EC directive :

- The purposes of the directive;
- the main provisions of the directive relative to patentable and unpatentable subject matter ;
- the particular case of inventions “derived from” elements of the human body (article 5)
- the extent of patent rights (article 8 and 9);
- An update on the latest developments relative to the studies at the European level of the patentability issues pertaining to inventions derived of elements of the human body;
- An up-date of the implementation of the EC directive (article 15) in the EU countries.

b) The Convention on the biodiversity (The Rio Convention) :

- Its main provisions;
- present status and latest developments.

16.00 ~ 18.30

Mr. René ROYON, Licensing consultant, Secretary general of CIOFORA (International Community of breeders of vegetatively reproduced ornamental and fruit-tree varieties), Mougins. France.

II – Plant breeder’s rights

- The legislative framework of plant variety protection (US Plant patents ; UPOV Convention 1961 / 1978 and 1991 and national laws of member countries ; Regulation EC/94/EC).
- The subject matter of plant patent / plant breeder’s compared with the subject matter of biotech patents.
- The general patent / plant breeder’s right interface.
- A survey of features common to the 98/44/EC directive and the 2100/94/EC regulation.

B - CAPITALISING ON INVENTIVENESS

09.30 ~ 12.30 Jacques BARTHOLEYNS, Executive director, strategy and intellectual property, IDM (Immuno Designed Molecules,) Paris.

I - INDUSTRIAL PROPERTY MANAGEMENT

1. *Specific significance of industrial property in the field of biotechnology :*
 - the high “added value” *versus* the cost factor of intellectual activity in the creation of new technology ; the share of industrial property rights among the overall assets of a biotechnological company ;
 - the significance of a patent portfolio relative to competitors ;
 - industrial property rights as the “hard” core underlying a new project – and business plan - of a “start-up” company ;
 - industrial property as a major vector of exchanges of technology.
2. *Integrating industrial property issues within applied research programs :*
 - watching innovations arising from creative efforts within the company and contemplating seeking protection thereof ;
 - providing for the staff’s awareness of industrial property issues.
3. *Managing industrial property budgets :*
 - appraising short term- and long term-costs, contingent and fixed costs of an acquisition policy of industrial property rights ;
 - determining balance of investment with initially uncertain return relative to new projects *versus* subsequent increase of costs relative to the completion of acquisition of industrial property rights for those subsequently upheld ;
 - apportioning parts of the budget devoted to these different kinds of costs.
4. *Constant up-dating of industrial property portfolio :*
 - giving up rights which have become obsolete or which have lost commercial interest for increasing parts of the budget devoted to protection of new creations.

 **Lunch**

14.00 ~ 16.00 Mr. Jacques WARCOIN, European patent attorney, Cabinet Regimbeau, Paris

II - INDUSTRIAL PROPERTY PROTECTION STRATEGIES IN BIOTECH

1. *Industrial property strategy* means the use of all possible industrial property tools : the patent is not the only one : they also include know-how, data bases, breeder’s rights unfair competition law, trademarks, software protection and sourcing protection.
2. *Industrial property strategy* requires a committee to manage a strategy and the important involvement of non-industrial property people.
3. *Patent strategy :*
via national, European, international patent applications, according to :
 - objectives ;
 - markets of interest ;
 - length of research work ;
 - significance of invention and extent of the protection sought ;
 - the time required to rise interest of prospective licensees in the invention ;
 - available budgets, etc...
4. *Strategy and network of rights to ensure best protection*

16.30 ~ 18.30 Mr. Eric LE FORESTIER, European patent attorney, Cabinet Regimbeau, Paris.

BIO-INFORMATICS

Specific problems pertaining to their protection.
Items to be completed by Mr Le Forestier.

Wednesday 21 January 2004

III - EVALUATING ONE'S OWN PATENT POSITION AND COMPETITORS' POSITIONS :

09.30 ~ 11.30 Mrs. Anne DESAIX, European patent attorney, Ernest Gutmann-Yves Plasseraud S.A., Paris.

1. *How to read patents and patent applications?*

- Checking whether they are in force ;
- The extent of protection determined by the patent claims ;
- Watching the successive steps of the proceedings relative to competitors' patent applications and patents, if ever granted ;
- Ascertaining the variations in scope of claims of such claims as time goes by.

2. *Patent dependencies*

- dependency *versus* patentability;
- patent and product dependencies;
- the rights of the owner of an older patent relative to the subject matter of a younger invention nevertheless encompassed by the claims of the older patent ;
- the rights of the owner of a patent pertaining to the younger invention relative to the owner of the older patent ;
- mutual patent dependencies and multi-patent dependencies.

3. *Compulsory licences and licences of right.*

4. *Auditing patent portfolios.*

 **Lunch**

IV - OTHER PROTECTION SYSTEMS:

13.30 ~ 14.30 Mr Giampiero DE LUCA, Chief Intellectual property Counsel and member of the executive board, Serono international S.A., Geneva

- Orphan drugs;
- Items to be completed by Mr de Luca.

C - AGREEMENTS

The matter is to be given consideration, first under three viewpoints, i.e. that of a party representing the academic research institutions, in their dealings with industry (**Mr. Bury**), that of a party responsible for the overall technology transfer policy based on the industrial property rights portfolio of a large biotechnological company (particularly, licensing-in and licensing-out) (**Mr. de Luca**) and that of the author of an invention, also having negotiated agreements pertaining to the exploitation of this invention (**Mr. Zabeau**). The fourth presentation (**Mr. Royon**) would tackle with the licensing problems specific to plant breeders' rights.

I - AGREEMENTS : THE VIEWPOINT OF THE ACADEMIC RESEARCH INSTITUTIONS

15.30 ~ 18.30 Mr. Jo BURY, Director general of VIB (Flanders Interuniversity Institute for Biotechnology), Gent, Belgium.

1. *Assignments of industrial property rights*

2. *Industrial property rights as part of the items exchanged in a technology transfer program.*

3. *Collaboration agreements between academic research institutions and industry for long range research and development programs :*

- defining domain of research and objectives sought;
- defining development and management of successive steps of research;
- the terms under which new results of the research can be subject to publication and to patenting : the mutual obligations in that respect of the parties to the agreement;
- providing as from the start whether options to a licence of the technology to be developed; are to be negotiated or not, etc. ...

THURSDAY 22 January 2004

II - AGREEMENTS : THE VIEWPOINT OF INDUSTRY

09.00 ~ 12.00 Mr, Giampiero DE LUCA, Chief Intellectual property Counsel and member of the executive board, Serono international S.A., Geneva.

- Licensing and negotiation issues at the level of a large biotechnological company ;
- exhaustion of rights, antitrust law issues, parallel imports ;
- patent update information to capture future trends and opportunities;
- major collaborations with academic groups, research-based and start-up companies.

Lunch

III - AGREEMENTS : THE VIEWPOINT OF THE INVENTOR... AND NEGOCIATOR

13.30 ~ 16.30 Mr Marc ZABEAU, Professor ; Scientific adviser, Department of Plant Systems Biology, VIB / Gent University, Director of Methexis Genomics, Gent.

The life cycle of a patented invention from conception to application and commercial exploitation, via the grant of licenses, up to its ultimate obsolescence : essential contractual clauses in the relevant licence agreements.

Of primary interest is the particular business environment in which the invention was brought to fruition, namely that of a typical biotech start-up with modest financial resources. The patent gave rise to different types of licence agreements – whose essential clauses will be reviewed ranging from straight forward product (kit) licences to more intricate right of use licences granting to third parties the right to internally make use of the novel technique. Other aspects of licence negotiations, including the difficult handling of the grey zone between bona fide research and disguised commercial exploitation by non profit organizations, will also be discussed”.

IV - SPECIFIC LICENCING PROBLEMS RELATIVE TO PLANT BREEDER'S RIGHTS:

17.30 – 18.30 Mr René ROYON, Licensing consultant, Mougins, Secretary general of CIOFORA.

Practical aspects of the exploitation of a plant variety, including strategic choices of the territorial area of the protection and timing of the filings, exploitation licences, dependencies of essentially-derived-plant varieties, controlling infringements, the influence of the trademark protection, the patent-plant breeder's interface.

FRIDAY 23 January 2004

D - ENFORCEMENT OF INDUSTRIAL PROPERTY RIGHTS :

09.00 ~ 12.30 Me Pierre VERON, Industrial property lawyer, Véron et associés, Paris, President of EPLA (European Patent Lawyers Association).

I. Different European countries : different proceedings

1. *A short comparison of the main steps of some national practices ;*
2. *The future community proceedings ;*
3. *Who can initiate action?*

II. Remedies against infringement

1. Attempts to avoid conflict :

- warning competitor deemed to infringe : to what extent?

2. Court actions :

- the available legal routes for the enforcement of industrial property rights ;
- preparing for court action ;
- who bears the burden of proof of infringement?
- availability of legal provisions for that purpose (in France : “saisie-contrefaçon”) ;
- filing suit : the successive steps of the proceedings ;
- preliminary injunctions;
- appointment of experts : in which circumstances and for which purposes ?
- appeals;

- which sanctions?
 - transnational execution, where possible, of the decisions of the courts.
3. *Other grounds in support of action :*
- infringement of other titles of industrial property ;
 - unfair competition.
4. *Damages: evaluations thereof.*

III. Defences against charges of infringement

1. *preventing infringement action*
- seeking from the patentee, subject to review by Court (when the relevant law permits) an acknowledgement of non-infringement
 - seeking limitations of claims to evade charge of infringement
 - nullity actions
2. *Defences against infringement action*
- raising inadmissibility of infringement action ;
 - challenging plaintiff's right to sue ;
 - seeking nullity of patent or restriction of the scope of the claims ;
 - raising grounds of bad faith.

IV. SETTLEMENTS

E - SYNTHESIS

12.30 ~ 13.15 Mr. Ernest GUTMANN, European patent attorney, Ernest Gutmann-Yves Plasseraud S.A., Paris

CLOSING THE SEMINAR

13.15 ~ 13.30 Pr Moncef GUENOUNOU, President of E.S.A.BIO, Ecole Supérieure d'Application des Biotechnologies, Paris.

 Lunch

E.S.A.BIO

Ecole Supérieure d'Application des Biotechnologies

Professional development for life science specialists.

Since our creation, we have developed a mission of delivering professional training for the management of technological innovation. Our hands-on training programmes - directly in phase with companies and scientists - integrate a solid transversal dimension, allowing us to take into account all the skills needed to drive a commercially-focused project forward. E.S.A.BIO. awards postgraduate diplomas in Bio-Management® and Bioinformatics Management®. These training programmes can be pursued on a full-time basis or in the form of modular "Competency Degrees". E.S.A.BIO. also organises training seminars: the "Défis Biotechnologiques de l'E.S.A.BIO"® (the E.S.A.BIO Challenges in Biotechnology), the "Défis Bio-Informatiques de l' E.S.A.BIO"® (the E.S.A.BIO Challenges in Bioinformatics) and training days for managers within the framework of I-Bio®, the Institute for Bio-Entrepreneurs®.

ECOLE SUPERIEURE D'APPLICATION DES BIOTECHNOLOGIES
POLE UNIVERSITAIRE LEONARD DE VINCI
92916 PARIS LA DEFENSE CEDEX



01 41 16 75 78



01 41 16 75 80



info.esabio@devinci.fr



www.esabio.fr

Association Loi 1901, N° SIREN : 784 615 502, N°SIRET : 784 615 502 00050, CODE APE : 803Z

Pricing & administration informations

MANAGEMENT OF INDUSTRIAL PROPERTY RIGHTS IN BIOTECH. : SHARING EXPERIENCES

Top executive management education program on Industrial Property.

19^h-23rd January 2004 Nice France

the web site of this event : <http://www.esabio.fr/manageIP.html>

Dead line for registration:

All registration forms for this event must be send before **Monday 15 December 2003**

Event Venue:

CUM

Centre Universitaire Méditerranéen
65 Promenade des Anglais - 06000 NICE - FRANCE
<http://www.cum-nice.org/index2.html>

Cost options for attending :

**MANAGEMENT OF INDUSTRIAL PROPERTY RIGHTS IN BIOTECH. : SHARING
EXPERIENCES. Top executive management education program on Industrial property.**

All fees include lunch, refreshments and conference papers if applicable. The fees for this event are as follows

MANAGEMENT OF INDUSTRIAL PROPERTY RIGHTS IN BIOTECH. : SHARING EXPERIENCES	5382 € (including French VAT 19.6%)
---	--

Registrations & Inquiries

To register for place(s) at this conference please print out the registration form and fax it to E.S.A.BIO. on (+33) (0) 1 41 16 75 80. If you would like to send your registration by mail, please print out the registration form and send it to:

E.S.A.BIO. Conferences
Pôle Universitaire Léonard de Vinci
92916 Paris La Défense cedex
France

Likewise all **questions** about this event should be addressed to ESABIO (info.esabio@devinci.fr)
No information will be given by phone

Payment

Delegates must ensure **that payment is received before 15 December 2003**. Payments made by cheque should be made payable to **ESABIO**. If you choose to pay by bank transfer, please tell

your bank to include the ESABIO reference code **ESBIO-Nice01** and the **delegate's surname** in the transfer instructions. Transfers should be made to:

Bank transfers (in Euro only) should be remitted to:

Crédit Industriel et Commercial (CIC)
14 PLACE DES TERRASSES DE L'AGORA
91000 EVRY
France

Account Owner	10874 00010277001 0468611 GUA
	ESABIO
Code Banque:	30066
Code guichet	10874
Account No	00010277001
Clé rib	71
IBANInternational Bank Account Number	FR76 3006 6108 7400 0102 7700 171
Bank Identification Code	CMCIFRPP

Please fax a copy of your bank transfer and the customer's name to our customer services department +33 (0)1 41 16 75 80

Cancellations & Refunds

We regret that no refunds can be made for cancellations received after the date of **15 December 2003**.

We welcome substitute delegates at any time.

It may be necessary for reasons beyond the control of the organisers to alter the content and the timing of the programme or the identity of the speakers.

Data Protection - Delegates Please Note

The personal information that you provide will be held on an ESABIO database and will not be shared with other companies in France and internationally.

This contract is covered by French Law.