



Licensing Executives Society
LES Benelux

Topic meeting – 11th of October 2012

Colonster Castle of the Sart Tilman University Campus, Liege, Belgium

Influence of Intellectual Property in health development; a barrier or an incentive?

Programme

8:30 - 8:45 Registration and coffee

8:45 - 9:00 Chair and Introduction: Nicole Antheunis, Patent Manager, Université de Liège

9:00 - 9:45 **Roy Waldron** Senior Vice President, Associate General Counsel & Chief Intellectual Property Counsel, Pfizer Inc., United States

The Future of the Pharmaceutical Industry: Is There an Innovation Crisis?

The pharmaceutical industry is now more than ever before under significant pressure to control the increasing costs of drug discovery, manage drug approvals in a more complex regulatory environment and contend with ever shorter effective patent life. Many companies are exploring new approaches to innovation in drug development, particularly by seeking non-traditional collaborations and arrangements to alleviate those factors within their control. Pharmaceutical collaborations involve the sharing of cost, expertise and risk – but in particular, strong intellectual property (IP) regimes and protections are necessary. Are there ways to build novel arrangements that bring the best innovation to the table but at the same time do not lose sight of the traditional protections? How does the industry meet the challenge of creating incentives for investment in drug discovery and development – are there legal solutions that get us there?

9:45 - 10:30 **Anthony Tridico** Managing partner of Finnegan's European office in Brussels, Belgium
Lessons learned from the field: Practical Examples of How to Utilize the Interplay between IP and the Regulatory Framework to Best Protect Your Pharmaceutical Inventions

More than any other market, understanding the interplay between patents and the regulatory framework in the Pharma market is crucial for devising a strategy for protecting innovation. Based on practical examples from pharmaceutical litigations, we will discuss effective strategies for building a strong patent portfolio. We will also discuss the due diligence process and what partners in the Pharma industry are looking for in an IP portfolio when analyzing a potential in-licensing opportunity.

10:30 - 10:45 Coffee break

10:45 - 11:15 **Eric Halioua** CEO and **Luca Falcicola** IP Manager, Promethera Biosciences, Belgium.
Value of IP to defend position in rare diseases and cell therapies : the example of Promethera Biosciences.

Promethera® Biosciences' mission is to discover, develop and commercialize cell therapy products to treat liver diseases in an innovative way using stem cell from healthy human livers. The company is a spin-off from the Laboratory of Paediatric Hepatology and Cell Therapy headed by Professor Etienne Sokal, an internationally renowned scientist and clinician in the field of paediatric liver diseases. Promethera® Biosciences was founded in 2009. The company has completed a 5.3 million euros A-round of funding complemented by 4M€ of loans and grants from the Walloon region end of October 2009. Promethera® Biosciences develops a new cell therapy product using allogeneic stem cells expanded from healthy human liver tissue. This product called Promethera® HepaStem aims to treat a wide variety of liver genetic and acquired diseases affecting children and adults. The innovation resides in both the simplicity of the treatment, which doesn't require radical surgery (compared to liver transplantation), and in the wide variety of liver pathologies that can be addressed with the same product. This product has received two orphan drug designations from the European Community for the treatment of Crigler-Najjar syndrome and the treatment of Ornithine transcarbamylase deficiency, and urea cycle disease. In conjunction, Promethera® Biosciences is developing, Promethera® HepaScreen, a unique cell model for the pharmaceutical industry to mimic metabolism and detoxification of new drugs by the human liver. Both products are based on a newly discovered and patented stem cell type: the human Adult Liver-Derived Mesenchymal Progenitor Cell (hALDMSC).

11:15 - 11:45 Frank Bulens Partner of the Health-tech Investment Practice, Capricorn Venture Partners, Leuven, Belgium.

IP: a crucial asset for a venture capital backed company!

This presentation will focus on the importance of intellectual property for a start up innovation based company active in the health-tech field. A spin off or early stage company needs to attract risk capital for its initial development and mostly IP is the main asset at that point. Also at later stage financings IP will be considered as one of the crucial assets. Even in case of an "Initial Public Offering" or a trade sale it will be considered as a necessary asset. In other words, from an (venture capital) investor view point IP is a crucial aspect from start to finish.

11:45-12:30 Laurent Manderieux , Professor of Law at Bocconi University, Italy.

Towards a balance in IP Licensing in Health issues?

The TRIPs Agreement, was revisited further to the Doha Declaration and the Decision of August 30, 2003 modifying Article 31. The Agreement now seems to provide a clearer legal framework for handling IP licensing in health matters. A brief review of such framework offers the merits of summarizing its advantages and drawbacks. Indeed, is this framework that transparent and effective *in practice* for business operators and licensing partners? Economic operators and governments are in any case exploring and using practical new solutions, permitted under the TRIPS flexibilities regime. How will this "TRIPS and" environment be shaped? Public-Private Partnerships (PPP) are one of the successful solutions found but many other options can also be used for a balance on the legitimate needs of business and the legitimate needs of promoting better access to Health.

12:30 - 14:00 Lunch

14:00 - 14:45 Konji Sebati, Ambassador (Dr.), Director, Department of Traditional Knowledge and Global Challenges World Intellectual Property Organisation, Switzerland.

WIPO Re:Search – A Unique Partnership to Address Research Barriers for Neglected Tropical Diseases

This is a WIPO initiative in collaboration with leading pharmaceutical companies, leading research institutes and academic institutions, to promote development of new drugs, vaccines and diagnostics to treat neglected tropical diseases, malaria and tuberculosis. The project was launched on October 2011. The guiding principles include the commitment that IP licensed via WIPO Re:Search will be licensed on a royalty-free basis for sale of neglected tropical disease medicines in or to least developed countries.

14:45 - 15:30 Roy Waldron, Associate General Counsel & Chief Intellectual Property Counsel, Pfizer Inc. , United States

Innovator Contributions to the WIPO Re:Search Consortium: Practical Aspects and Issues

15:30 - 15:45 Coffee break

15:45 - 16:15 Jean-Michel Foidart CSO UTERON Pharma s.a., founder of MITHRA Pharmaceutical s.a. and Professor at University of Liège (Belgium)

North-South Partnership : An example in contraception«

16:15 – 16:45 Florence Xhonneux - Business Development Manager and **Stéphanie Blavier**, Legal Advisor EUROGENTEC (Belgium)

How do Contract Manufacturers manage IP? - A testimony

In these rapidly changing economic, technological and regulatory environments, both SMEs and the pharmaceutical industry are working with a wide range of outsourcing partners rather than investing in new plants, equipment and personnel as a means of managing uncertainty. How are IP rights of each partner in that context managed? What are the potential issues? Are practices different for neglected diseases? Presented here is a testimony from a Contract Manufacturing Organization that uses its know-how and proprietary technologies since 1994 to develop specific manufacturing processes for new vaccines and therapeutics on behalf of SME, big pharma and non-profit organizations.

16:45 Networking Cocktail

Resumes speakers, moderators and chair

Nicole Antheunis Dr, CLP, is Patent Manager at Université de Liège since 1999. She is also senior lecturer of Intellectual Property at the University. Nicole is a member of LES Benelux, ANBPPI, CIPA, LIEU and PROTON Europe. She is actively involved in the Exam Development Committee for Certified Licensing Professionals. Nicole has worked earlier in his career as research scientist and patent agent at Dow Corning. She is Doctor in Science from ULB and has learned Intellectual Property at Université de Strasbourg.

Stéphanie Blavier – Legal Advisor, General Secretary, Eurogentec S.A. Stéphanie joined Eurogentec in 2000 to establish the legal department. She has experience in numerous types of contracts in the area of life science research, and diagnostic and pharmaceutical contract manufacturing. Her expertise includes drafting and negotiation of distribution, master service and license agreements. Stéphanie is a member of the Benelux License Executive Society, a member of the University of Liege's Law and Business Life Commission, and a board member of the Belgian Institute of Company Lawyers.

Frank Bulens is Partner Health-tech Investment Practice at Capricorn Venture Partners, a Leuven based pan-European manager of venture capital funds seeking to invest in technology-based growth companies. Before joining Capricorn Venture Partners end of 2009 Frank served as an Executive Investment Manager in the venture capital life science team at Gimv where he was actively involved with several investments in life science companies across Europe and in the US most of which were acquired or became public quoted. Before Gimv he was a Senior Scientific Advisor at IWT, a research fund organisation in Brussels following an academic career at the Faculty of Medicine, University of Leuven. He also did research in the food industry (Diadal, now part of Nutricia). Frank is an Engineer in Chemistry/Biochemistry and has a PhD in Medical Sciences.

Jean-Michel Foidart is MD, PhD. He graduated from the University of Liege in 1974 and was trained in the USA at the National Institutes of Health (Bethesda) and at Johns Hopkins Hospital, Baltimore from 1976 until 1979. He also spent several months of training in France, Finland and a sabbatical year in Montreal, Canada in 2004. He has been the Chairman of the Department of Cell Biology from 1987 until 1997 at the University of Liege and subsequently, he became the Chairman of the department of Obstetrics and Gynaecology at the same University, from 1996 until 2011. He is presently the president of the College Mother and Newborn. He is an expert at the FNRS and FWO. He also serves as Jury member of the Prestigious Interbrouw Baillet Latour Prize. He is member of the Academies of Medicine of Belgium and France. He was nominated Doctor Honoris Causae of the Universities of Paris 5, Pierre et Marie Curie-La Sorbonne in 2010 and of the University Paul Sabatier in Toulouse in 2012. In 1999 he created with F. Fornieri a spin-off at the University of Liege, Mithra, to develop the patents granted to his Biology and Research Lab. Mithra has now grown up and has more than 200 scientists and employees. In 2012, he has become an Extraordinary professor at the University of Liege and presently conducts the medical research at Mithra-Uteron and at the GIGA at the University of Liege.

Laurent Manderieux is Professor of Intellectual Property Law at L. Bocconi University of Milan, Italy, Associate Professor of Copyright Law at the University of Francophone States, Visiting Professor of Intellectual Property Law at the University of Trento, Italy, Contract Professor of Intellectual Property Law at the State University of Milan, Italy, and invited Professor / Lecturer of Intellectual Property Law in Universities and Training Institutes in many countries of Europe, the Americas, Asia, and Africa.

In addition to his IP teaching and IP research activities, he is Senior Intellectual Property Expert for various international Organisations (WIPO, UNDP, UNCITRAL, OIF, IDLO, etc) and Governments. Among his various capacities, he was Head, World Intellectual Property Organization (WIPO) Public Affairs and Media Relations, also in charge of IP training and information for government officials, lawyers, researchers, scientists, and business circles. He is the author of numerous IP training material and publications. He held Conferences on most key IP subjects in many industrialized and developing countries and also worked earlier in his career for the Food and Agriculture Organization of the UN (FAO) in Rome, Italy, and at the European Union in Brussels.

Eric Halioua is the CEO of the Belgian Biotechnology company Promethera Biosciences. Promethera® Biosciences' mission is to discover, develop and commercialize cell therapy products to treat liver diseases in an innovative way using stem cell from healthy human livers. Eric is co-founder of two biotechnology companies called Myosix and Murigenetics. Myosix is a tissue engineering company specialising in musculoskeletal cells culture used in the regeneration of the heart muscle. The company has been sold to Genzyme mid-2002 that financed the phase 2 of clinical trial. Murigenetics is a Biotechnology company developing therapies for genetic disorders. Eric was also a Board Member of a French public biotechnology company called Vivalis, which specializes in the production of avian stem cells lines for the production of vaccines and recombinant proteins. Eric was as well principal of the international life sciences practice of Arthur D. Little based in Paris and Boston during 11 years. He has led and conducted work in the areas of strategy, M&A and technology & innovation management for biotechnology, pharmaceutical and medical devices companies. Eric also worked as a strategic marketing manager for the "Centre Européen de Bioprospective" and as project leader in the corporate R&D centre of Zeneca in UK. Eric holds two master degrees (DEA and Magistère) in Pharmacology and Molecular Biology and a MBA from ESSEC business school (Paris, France), with an advanced degree from the Health Care ESSEC chair.

Ambassador Konji Sebati (Dr.) is a medical practitioner by training and later obtained a Diploma in Child Health and a Diploma in Public Health Planning and Health Services Management. Before joining the diplomatic service, she worked in the pharmaceutical industry; as a Medical Advisor and Medical Director for Roche Pharmaceuticals and Pfizer Pharmaceuticals in South Africa, respectively, in charge of Clinical Research, Product registration, Safety and Pharmacovigilance, Quality Assurance, and Sales force training. She had the honour of being appointed Ambassador of the Republic of South Africa to Switzerland, The Vatican and Liechtenstein, and subsequent to that Ambassador to France/UNESCO and OECD, before joining WIPO as Director, Department of Traditional Knowledge and Global Challenges, World Intellectual Property Organisation (WIPO); Global Issues Sector in 2010.

Anthony Tridico is the managing partner of Finnegan's European office in Brussels, Belgium. He practices all aspects of intellectual property law, from strategic patent portfolio management to litigation. Dr. Tridico's practice involves diverse technical areas, focusing on pre-litigation analysis and strategic client counseling, due diligence investigations, licensing, patent portfolio management and analysis, prosecution of both U.S. and foreign patent applications, and appeals and oral hearings at the Board of Patent Appeals and Interferences. He also offers expertise in representing clients in the specialized areas of patent reexamination, including inter partes reexam, reissue, FDA Orange Book listing of patents, and patent term extensions. Strategic portfolio management and counseling to European clients is an important part of Dr. Tridico's practice. During his previous tenure in Brussels (2001-2004), he gained significant knowledge about the EPC and the diversity of laws and practice among the European national systems. His knowledge of the European legal system and how it differs from the United States allows Dr. Tridico to effectively counsel both European and U.S. clients with global interests in intellectual property.

Roy F. Waldron, Senior Vice President, Associate General Counsel & Chief Intellectual Property Counsel, Pfizer Inc, United States. Roy F. Waldron is Senior Vice President, Associate General Counsel and Chief Intellectual Property Counsel at Pfizer Inc. He leads the team of Pfizer attorneys and professionals worldwide who procure patents, work closely with R&D, Business Development and the Pfizer Business Units, and ensure enforcement of trademarks. Roy represents Pfizer on the committees of various industry organizations, including IFPMA, PhRMA, where he is chair of the IP Task Force, IPO, where he represents Pfizer on the Board of Directors, and INTERPAT. Roy joined Pfizer in 1999 from White & Case's IP practice group, and was also previously an associate at Fish & Neave. Roy has a JD from New York University School of Law, a PhD from Yale University (physical-organic chemistry) and a BA from Dartmouth College (chemistry). He was a DAAD Scholar at the Albrecht-Ludwigs-Universität in Freiburg Germany and a JSPS Post-Doctoral Fellow at Kyoto University in Japan.

Florence Xhonneux is a Business Development Manager at Eurogentec. Florence has a Ph.D. in Biological Sciences from the University of Liège. She joined Eurogentec in 1987 when Eurogentec was founded and worked on Eurogentec's vaccine development programs. From 1995 to 1997 she managed the molecular biology activities and then became Head of Process Transfer & Development until 2005. From 2005 to 2007 Florence managed the Biologics division's Sales activities. Since 2007, Florence identifies, analyses and manages new collaborations and technology development opportunities that allow Eurogentec to meet trends and future needs of the biopharmaceutical market.

Location and directions

The meeting takes place at the Colonster Castle, University, Allée des Erables, B-4000 Liège, Belgium. Phone +32 4 366 3020; fax +32 4 366 4595; www.colonster.ulg.ac.be/english/index.html.

Registration

The fee for this meeting will be € 100,00 for LES Members, members of Proton and members of the University of Liege, and € 150,00 for non-members. The fee includes meeting materials such as programme and participants list, buffet lunch, coffee and tea in the break and drinks after the meeting.

Granting of study hours and educational points

For Dutch Lawyers the amount of study hours is five (5). The Belgische Balies granted 5 educational points. Please contact the Registration Desk for the necessary lists to sign.

Membership

For information on membership of LES Benelux please e-mail to membership@les-benelux.org and more information with an application form will arrive at your desk within a few days. Membership information is also available on www.les-benelux.org.

Program and presentations

The speakers at this meeting have been requested to make their presentations available for publication at level 2 (registration required) of the before mentioned web site. The presentations will be available approximately two weeks after the meeting.