



# FIT Pharma Summit

April 13, 2018



**Farma Industria Ticino**

Event planned in collaboration with

**CREDIT SUISSE** 

*«The life science valley  
in the heart of Europe»*



**Farma Industria Ticino**

# The Ticino pharmaceutical industry continues to expand and build a bright new future

Farma Industria Ticino (FIT) - the association of the Ticino chemical and pharmaceutical industry - represents a leading industrial sector and a key contributor to the economy of the Ticino region. With 28 member companies, FIT represents a total workforce of over 2,900 employees and generates a combined annual turnover of approximately 2.45 billion Swiss francs, which equates to approximately 8.5% of the regions GDP. Several investments accounting nearly half billion Swiss francs have been planned in Ticino from 2016 to 2018, mainly in R&D and innovation.

Growing competition, globalization, and the introduction of new rules and regulations within the industry, continue to make the art of leading a company both increasingly challenging and highly demanding. To deliver success in such an evolving and complexed environment requires leadership and drive of the highest degree from top performing boards working in unison with senior executives with strategic vision and operational skills.

The FIT Pharma Summit has been conceived as the premier gathering for Board members and Senior Leaders to share information, gain common understanding, discuss the future trends in our industry and to ultimately build the ideal environment for sustainable growth.

# Programme

08:30 – 09:00	Arrival and refreshments	
09:00 – 09:10	<b>Welcome by Farma Industria Ticino (FIT)</b>	<b>Giorgio Calderari</b> Chairman of the Board of FIT General Manager, Helsinn Group
09:10 – 09:15	<b>Welcome by Lugano Municipality</b>	<b>Marco Borradori</b> Mayor of Lugano
09:15 – 09:30	<b>Welcome by Credit Suisse</b>	<b>Thomas P. Gottstein</b> CEO, Swiss Universal Bank and Credit Suisse (Schweiz) AG

## *SESSION I* *Financial Ventures*

09:30 – 10:10	<b>Finance I</b> <ul style="list-style-type: none"><li>Alternative financing solutions for mid-market companies</li></ul>	<b>Ottavia Tuinhout</b> Director, Corporate and Investment Banking, Credit Suisse (Schweiz) AG
10:10 – 10:40	<b>Finance II</b> <ul style="list-style-type: none"><li>Valuation of Life Science companies</li></ul>	<b>Johannes Post</b> Partner, Deal Advisory, KPMG
10:40 – 11:10	<b>Q&amp;A</b>	<b>Eric Cornut</b> Moderator
11:10 – 11:40	Coffee break	

## *SESSION II* *Intellectual Properties*

### THE EU PERSPECTIVE

11:40 – 12:20	<b>Patent exclusivity in Europe</b> <ul style="list-style-type: none"><li>Patent-Based and Non-Patent Based Exclusivities in Europe</li><li>How to navigate between patents, supplementary patent certificates and pediatric extensions</li><li>Connections between the Patent exclusivity and Regulatory Requirements for Generic Filings</li></ul>	<b>Marion Chajmowicz</b> Becker & Associés
12:20 – 12:50	<b>Case Study</b> <ul style="list-style-type: none"><li>The Cialis® (tadalafil) patents in Europe: protection strategy and challenges</li></ul>	<b>Marion Chajmowicz</b> Becker & Associés
12:50 – 13:20	<b>Q&amp;A</b>	<b>Eric Cornut</b> Moderator

13:20 – 14:45 Business Lunch offered by 

## THE US PERSPECTIVE

14:45 – 15:20	<b>Understanding ANDAs, 505(b)2, Paragraph IV Patent certifications</b> <ul style="list-style-type: none"><li>▪ Laws and Regulations Definition</li><li>▪ Hatch-Waxman Act</li><li>▪ Orange Book</li><li>▪ Regulatory Requirements for Generic ANDA and 505(b)2 Filings</li><li>▪ Patent-Based and Non-Patent Based Exclusivities</li><li>▪ Patent Certifications</li><li>▪ Paragraph IV Patent Certifications</li><li>▪ Reference Listed Drug (RLD)</li><li>▪ ANDAs Containing a Paragraph IV Certification</li><li>▪ 505(b)2 and "equivalency"</li></ul>	<b>Chad J. Peterman</b> Partner, Litigation Department Paul Hastings
15:20 – 16:00	<b>Patent litigations</b> <ul style="list-style-type: none"><li>▪ Post Grant Reviews at the US Patent office (new regulation)</li><li>▪ Civil court process (discovery, trial, appeal, etc.)</li><li>▪ Citizen petitions</li><li>▪ Patent issues: non-infringement, invalidity (on-sale bar, ready for patenting, inventor ship, obviousness, etc.)</li><li>▪ Settlement opportunities (including antitrust issues)</li></ul>	<b>Eric W. Dittmann</b> Partner, Litigation Department Paul Hastings
16:00 – 16:20	Coffee break	
16:20 – 17:05	<b>Case Study</b> <ul style="list-style-type: none"><li>▪ Helsinn vs "the others"</li></ul>	<b>Joseph O'Malley</b> Partner, Litigation Department Paul Hastings
17:05 – 17:35	<b>Q&amp;A</b>	<b>Eric Cornut</b> Moderator
17:35 – 17:50	<b>Final remarks</b>	<b>Giorgio Calderari</b> Chairman of the Board of FIT General Manager, Helsinn Group
17:50 – 19:00	<b>Networking refreshment</b>	
19:00	Dinner	

# Keynote speakers



## Giorgio Calderari

Chairman of the Board of Farma Industria Ticino.

Giorgio Calderari is the General Manager and Chief Operating Officer for the HELSINN GROUP and Member of several Boards of Directors of the HELSINN GROUP. He has overall responsibility across the entire Group with supervisory responsibility of R&D, scientific operations, manufacturing affairs, commercial operations, finance & administration, legal affairs and information technology. Giorgio has extensive experience in managing drug development, supply chain establishment and worldwide launches for a number of New Chemical Entities which have gained approval from the world's major regulatory authorities and are currently sold in more than 90 countries. Past experience of note also included positions as Chief Manufacturing Officer and senior management in chemical plants (third parties manufacturing) as R&D, business development and quality manager.

Giorgio graduated in chemistry and obtained a PhD at the Swiss Federal Institute of Technology (ETH) in Zurich.



## Eric Cornut

Eric Cornut is an independent consultant and non-executive board member in the area of Healthcare, who most recently, served as Special Envoy to the CEO of Novartis. From 2014 to 2016, Mr. Cornut held the role of Chief Ethics, Compliance and Policy Officer of the Novartis Group, in addition to that of Chairman of Novartis Group Japan.

Previous to this, Mr. Cornut has held positions as Chief Commercial Officer of Novartis Pharmaceuticals led Pharma Europe. Prior to that, he served as Chief Executive Officer of Novartis Netherlands and Novartis France, and played a key role in the merger of Ciba-Geigy and Sandoz.

Eric Cornut has a Doctoral degree in Law from the University of Basel, Switzerland, and a Master of Law degree from the University of California, Berkeley, USA.



## Thomas P. Gottstein

Thomas P. Gottstein is the CEO Swiss Universal Bank, the CEO of Credit Suisse (Schweiz) AG and a member of the Executive Board of Credit Suisse Group AG. He is based in Zurich. Before assuming his current role he served as the Head of Premium Clients Switzerland & Global External Asset Managers within the former Private Banking & Wealth Management division from 2013 to October 2015. From 2009 to 2013 he was the Head of Investment Banking Coverage Switzerland and Co-Head of Credit Suisse's European Equity Capital Markets team, part of the Global Market Solutions Group (GMSG), from 2007 to 2009. Mr. Gottstein joined the Investment Banking Department of Credit Suisse First Boston in Switzerland in 1999. He began his career at UBS where he held several positions. He has over 20 years of banking experience, including 13 years in London. Mr. Gottstein holds a PhD in Finance and Accounting and a degree in Business Administration and Economics from the University of Zurich.



## Ottavia Tuinhout

Ottavia Tuinhout is a Director of Credit Suisse, in the Corporate and Investment Banking division, based in Zurich, Switzerland. She is part of the Mid Market Lending team, structuring non-standard financing solutions for mid-market companies. She has extensive experience in senior debt, mezzanine and equity investments across Europe. She joined Credit Suisse in January 2018. Prior to Credit Suisse Ottavia worked over ten years in London at Intermediate Capital Group, a specialist asset manager, focusing on mezzanine financing of private equity transactions, and at Greenpark Capital, a fund of fund providing liquidity to private equity investors. She started her career in the consulting division of Deloitte focusing on banking and insurance clients, in Boston and Milan. She holds a BA in Business Administration summa cum laude from Babson College (Boston, USA) and a Master in Finance from London Business School (UK).





## Johannes Post

Deal Advisory partner of KPMG in Switzerland. He gathered experiences in Corporate Finance for more than 16 years with KPMG assignments in Munich, New York and since 2008 in Zurich. Johannes leads KPMG's Swiss and EMEA Valuation Services practices and preforms business valuations as well as valuations of intangible assets, such as brands and technology, in the context of sell side and buy side mandates, for joint ventures, or dispute resolutions. Johannes advises his clients on value management topics, such as portfolio analysis or value decision based concepts. He regularly provides fairness opinions and other independent valuation services, e.g. for financing or restructuring purposes. Valuations for financial reporting (IFRS and US GAAP) and for international tax planning is also a key area of his expertise. Throughout his career Johannes served many life science companies, global firms as well as start-ups, private equity firms, VCs, asset manager and funds. Johannes regularly gives lectures at the University of St. Gallen and other academic institutions.



## Marion Chajmowicz

Marion Chajmowicz is a European Patent Attorney whose knowledge and expertise have been drawn from her work in IP law firms, since 1996, both in France and in the United States. She joined Becker & Associés, a boutique IP law firm located in Paris, in 2005, and became a partner of the firm in 2007. Marion has a Master Degree in Pharmacology, from the University of Nice (France). She also graduated from the International Patent Law School (CEIPI) in Strasbourg, as well as from the European Patent Litigation Course.

Marion values the diversity of her clients - from start-ups to major pharmaceutical companies, as well as generic companies - and provides tailor made advice to each of them. She builds and consolidates patent portfolios, and further conducts studies of freedom to operate and due diligence operations.





## Chad J. Peterman

Chad J. Peterman is a partner in the Intellectual Property practice at Paul Hastings and based in the firm's New York office. Mr. Peterman is a first-chair trial and appellate attorney with a practice that focuses on patent and antitrust litigation with an emphasis on life sciences and technology. He has lead cases for many branded pharmaceutical companies including Abbott, Takeda, Johnson & Johnson, and Orexigen. He has been recognized by Managing Intellectual Property magazine's as a "Life Sciences Star" in North America. In addition to litigation, Mr. Peterman also represents companies in a variety of intellectual property transactional matters. He received his J.D. from Georgetown University Law Center and B.S.E. in Electrical Engineering from Princeton University.



## Eric W. Dittmann

Eric W. Dittmann is a partner in the Intellectual Property practice of Paul Hastings and is based in the firm's New York office. Mr. Dittmann has extensive experience litigating high-stakes patent cases in a range of technologies, with an emphasis on the pharmaceutical and biotechnology fields. His numerous high-profile victories have been acknowledged by various legal publications, including LMG Life Sciences, Law360, and Benchmark Litigation. Before entering private practice, Mr. Dittmann served as a judicial law clerk to the Honorable Alan D. Lourie of the United States Court of Appeals for the Federal Circuit. He received his J.D., *summa cum laude*, from Seton Hall Law School, where he was an Associate Editor of the Seton Hall Law Review. He also received a B.S. in Mechanical Engineering, with High Honors, from Rutgers University College of Engineering.



## Joseph O'Malley

Joseph M. O'Malley, Jr. is the Global Head of Intellectual Property at Paul Hastings, overseeing the firm's 100 plus lawyer IP practice. He has extensive patent litigation experience across a broad range of technologies, including chemicals and pharmaceuticals. Mr. O'Malley has served as lead trial counsel for many branded pharmaceutical clients including Pfizer, Merck, Abbott, Eisai, Sepracor, and Nycomed, and has prevailed at trial and appeal in billion-dollar-a-year Hatch-Waxman Act pharmaceutical patent litigations. Prior to law school, Mr. O'Malley worked for seven years as a chemical engineer in DuPont's engineering department. He received his J.D., with honors, from Rutgers-Camden School of Law and his B.S. in chemical engineering *with highest honors*, from Rutgers College of Engineering.

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# Location



## Lake front & 10 minutes to City Center

The Grand Hotel Villa Castagnola resort is right on Lake Lugano and a short walk from the town centre, where you'll find the Palazzo dei Congressi, museums, casino and shops.

## Distances

km 0.3 (0.2 miles) from the Padiglione Conza (Centro Esposizioni)  
km 0.5 (0.3 miles) from the Palazzo dei Congressi  
km 2 (1.2 miles) from railway station  
km 4 (2.5 miles) from motorway, A2 exit  
km 7 (4.4 miles) from Lugano Agno Airport  
km 62 (39 miles) from Milano Malpensa Int. Airport  
km 84 (52.2 miles) from Milano Linate Int. Airport  
km 215 (134 miles) from Zürich Int. Airport

## Parking

The garage entrance of the Grand Hotel Villa Castagnola is located in Via Pico 9-13, 6906 Cassarate.



## Grand Hotel Villa Castagnola

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## Organisation offices



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