

# IIPRO

And



**Khurana & Khurana, Advocates And IP Attorneys**

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**03**  
DAYS

**THREE - DAYS INTERNATIONAL SYMPOSIUM  
ON PHARMACEUTICAL, BIOTECHNOLOGY & CHEMICAL PATENT LAWS**

For R&D SCIENTISTS & IP PROFESSIONALS

**25-27th September 2017**  
AT HOTEL HILTON (ANDHERI EAST), MUMBAI

**27-29th September 2017**  
AT STELLAR GYMKHANA,  
GREATER NOIDA (DELHI-NCR) RESIDENTIAL



## ABOUT THE SYMPOSIUM

With Patents becoming a core part of existing economic ecosystem, particularly for Pharmaceutical, Biotechnology, Chemical, and Drug Industries, creation and exploitation of Patent Portfolio has become an industry in itself; especially with the cost of development and protection of the portfolio being enormous. It is therefore crucial to understand important Patent issues, not only for IP teams but even more importantly for R&D Scientists so as to minimize efforts in Patent development and maximize commercial gains. It is also important for Corporate and concerned stakeholders to understand nitty-gritties of Patent portfolio creation, promotion, protection, management, and commercialization, without which there would always remain an open door for a serious blow either from an infringement perspective or from a patent invalidation perspective or the portfolio would remain under commercialized. This is precisely why the number of major patent litigations are growing between competitors and contemporaries, besides the growing threat from international exploiters.

Exclusivity rights granted through patents can only be utilized if there is comprehensive knowledge of various patent related issues, more so when the National Patent Laws & Practices relating to prosecution practices, drafting practices, examination practices, enforcement practices and commercialization practices differ substantially across geographies. Furthermore, standards for protection and enforcement as applied by different National judiciaries often vary widely and therefore in global business scenario, besides understanding of Patent Laws and Practices prevalent in India, we also need to understand practices in economically and financially important geographies such as in United States, Europe, Japan and Brazil. It is in this direction that the three days International Symposium is being organized to impart comprehensive knowledge to understand nitty-gritties of Patent Regime.

### **HOW THE SYMPOSIUM IS UNIQUE**

This Symposium features presentation of all important patent issues as mentioned in this brochure. The speakers are a unique gathering of Patent Attorneys, Litigators and Legal Counsels who have extensive years of experience in their professional fields and are well acquainted with the Industry's need. These speakers will put across to the delegates the real insight of Patent Laws, Practices and Commercial perspectives as prevalent and practiced in United States, Europe, Japan, India and Brazil. The Workshop will provide an opportunity to receive first-hand information including recent Judgment on various issues from the experts in the fields. The speakers are selected such that R&D Scientists, In-House Counsels, Patent Attorneys, and IP Practitioners can get to know real insights and nitty-gritties followed in the United States, Europe, Japan, India and Brazil in Patent Domain. The speakers would share real-life cases and experiences that can help attendees in following best practices for building their respective patent portfolios so as to best commercialize.

### **RESIDENTIAL PROGRAMME AT GREATER NOIDA (DELHI-NCR)**

Programme at Greater Noida shall cater to both Residential as well as Non-Residential delegates. Residential arrangements for 3 nights have been made on most conservative rates with required conveniences. Residential delegates shall be picked up and dropped at the Airport/Railway Station. Organizers have also made arrangement for delegates who wish to visit Agra and see Taj Mahal at no additional cost. Delegates who wish to join for Agra visit would need to arrive at Delhi Airport/Railway station before 0800 hrs on 26th September 2017 so as to reach Greater Noida before 1000 hrs so that all can leave for Agra by 1000 hrs on 26th September 2017 after keeping their belongings at the hotel. After seeing the Taj Mahal, delegates shall be brought back to the hotel by about 2000 hrs so as to go through with the programme on the next day.

### **WHO SHOULD ATTEND**

IP Management Teams, Research & Development Scientists, Patent Agents & Attorneys in the field of Practice, Patent Litigators, Professionals in Legal-Business domain related to Pharma, Biotech and Chemical Industry.

## REGISTRATION FEES

### Indian Delegates:

**Non Residential Delegates:** INR 15,000 Per Delegate (If 3 or more delegates are nominated by any company, delegate fees will be INR 12,000 Per delegate)

**Residential Delegates:** Over and above the delegate fees as mentioned above, each residential delegate shall pay

- (i) INR 14,000/- for 3 days stay (26-28th September) at Resort Stellar Gymkhana inclusive of B'fast + Pick and drop from Airport/Railway station. Total 12 rooms available on first booking basis
- (ii) INR 10,000/- for 3 days stay (26-28th September) at Grand Heritage Resort inclusive of B'fast + Pick and drop from Airport/Railway station. Total 10 rooms available on first booking basis
- (iii) Dinner shall be organized on 27th September and all delegates shall be requested to join the speakers

### Foreign Delegates:

**Non Residential Delegates:** USD 300 Per Delegate

**Residential Delegates:** Over and above the delegate fees as mentioned above, each residential delegate shall pay USD 400 for 4 nights from 26th to 29th September at Resort Stellar Gymkhana where the programme is arranged; with pick up and drop to Airport and all meals at the resort (Total Delegate Fees USD 700)

### Visit to Agra:

Visit to Agra, for Residential Delegates, to see the Taj Mahal shall be made on 26th September 2017 by road and all arrangements shall be made by the organizers at no additional cost. Residential Delegates who wish to join must reach Greater Noida before 1000 hrs on 26th September 2017.

## NOMINATION FORM

Please Forward the Delegate Fees with the following details:

Name, Organization, Designation, Address and Contact Details along with the cheque to be drawn in favour of:

" M/S IIPRD" addressed to:

Ms. Meenakshi Khurana , IIPRD, E-13, UPSIDC Site-IV, Kasna Road, Greater Noida-201308, UP, India

Or

Transfer Funds to our Bank; details are as Follow:

Name of the Account Holder: M/S IIPRD

Bank Name: UCO Bank Branch, Branch Name: Greater Noida

Bank Account Number: 19620210002476

Bank Address: G.N. Shopping Plaza, Plot No.-S-7/1, Site-IV, Kasna Road, Greater Noida

MICR Code: 110028055

IFSC Code: UCBA0001962

### FOR ANY QUERY CONTACT:

R. Srinivasan (IIPRD)

(M): +91-9716064337 (T): +91-120-4296878, 4909201, 4516201

E: Srinivas@iiprd.com



# PROGRAMME OUTLINE

## [US Scenario]

### **0900 - 0930 : Registration**

#### **0930 - 1030 : Session - I**

Exploring the ramifications of the Federal Circuit's first decision interpreting 35 USC 102 as amended by the AIA: *Helsinn Healthcare v. Teva Pharms.* Analyzing the on-sale bar provision of the Patent Act as amended by the AIA: comparison to pre-AIA statute. Understanding how the language of the amended statute led to the District Court's finding that a non-public, secret sale did not trigger the on-sale bar provision to invalidate the patent.

#### **1030 - 1145 : Session - II**

Understanding how the Federal Circuit's obviousness ruling in *Apple Inc. v. Samsung Electronics Co. Ltd.*, may impact obviousness findings in life sciences patents. Review of recent obvious decisions involving Paragraph IV litigation at the District Court, PTAB and Federal Circuit; impact of *Cuozzo*. Re-visiting secondary considerations. Double Patenting Type Obviousness: *Bayer Pharma AG v. Watson Labs., Inc.*

#### **1145 - 1200 : Tea Break**

#### **1200 - 1315 : Session - III**

Impact of the Federal Circuit's decision in *Novartis v. Noven* upholding the invalidation by the PTAB. Highlighting winning strategies for both patent owners and challengers; Lessons for patent prosecutors that emerge from PTAB practice. Review of the recent wins and losses at PTAB: *IPR vs. PGR vs. CBM*; *Altaire Pharmaceuticals, Inc. v. Paragon BioTeck Inc.* The relationship between district court Hatch-Waxman litigation and PTAB challenges: impact of *Cuozzo*.

#### **1315 - 1415 : Networking Lunch**

#### **1415 - 1515 : Session - IV**

Best Practices for Claim Construction: summarizing current law post *Nautilus, Inc. v. Biosig Instruments, Inc.* and *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* Discussing best practices and advice for patent practitioners regarding claim construction when drafting patent applications, giving patent infringement opinions, or litigating a case.

#### **1515 - 1615 : Session - V**

Discussion on determining subject matter patentability of method patents in life sciences domain based on Federal Circuit's decision in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.* and prior 101 jurisprudence post-*Myriad*. Comparison of Federal Circuit findings in *CellzDirect to Endo v. Actavis* and *Vanda Pharmaceuticals Inc. v. Roxane Laboratories, Inc.*: decisions involving 101 challenges to Orange Book listed method claims. What to draw from this jurisprudence with respect to drafting subject matter eligible method claims and bringing 101 motions?

#### **1615 - 1630 : Tea Break**

#### **1630 - 1730 : Session VI**

Exploring the ITC as an alternate forum in an ANDA challenge: Examining the pros and cons of using the ITC in an ANDA challenge. Update on Reverse Payment Settlements and other Antitrust developments concerning Brand name and Generic interests. How new PTO leadership may affect pharmaceutical patents and Hatch-Waxman strategies. Understanding what changes at FDA may mean for Orange Book patents. Anticipating how possible changes at FTC may impact the future of "pay for delay" enforcement and investigations.



# PROGRAMME OUTLINE

## [US Scenario]

### **0930 - 1100 : Session - VII**

Examining uncertainties in the boundaries of 271(e)(1) and the scope of Divided and Induced Infringement: Understanding which post-approval activities fall within the scope of the safe harbor as per *Amphastar Pharmaceuticals, Inc. v. Momenta Pharmaceuticals, Inc.* Review of the pre-approval v. post approval debate under 271(e)(1). Examining the state of the law on divided infringement and its implications for *Hatch-Waxman*; *Akamai* standard; *Eli Lilly and Company v. Teva Parenteral Medicines*. Understanding situations in which infringement can be alleged through safe harbor violation and inducement.

### **1100 - 1115 : Tea Break**

### **1115 - 1215 : Session - VIII**

Review and impact of *Mayo*, *Myriad*, and *Ariosa* decisions on recent USPTO and Federal Circuit decisions addressing 101 rejections for biotech patents. Review of the USPTO guidance on 101 patent eligibility. Strategies to overcome 101 rejections. Tips on robust patent specification and claim drafting.

### **1215 - 1330 : Session - IX**

Leveraging Patent Design Arouds: What factors should be considered when seeking a design around of a valid patent to reduce risk of patent infringement? and what steps should be taken when drafting patent applications to minimize the likelihood that competitors can design around the patent? What role do design arounds play in the context of damages?

### **1330 - 1430 : Networking Lunch**

### **1430 - 1530 : Session X**

Proving and Avoiding Inequitable Conduct in Patent Prosecution and Litigation. Discussing the most common assertions defendants make when raising inequitable conduct defense. Best practices to be employed by prosecutors and litigators when pursuing and defending inequitable conduct allegations. What guidance do post-*Therasense* decisions and the USPTO proposed rules provide on how inequitable conduct will be treated?

### **1530 - 1545 : Tea Break**

### **1545 - 1645 : Session XI**

Discussion on the ongoing Jurisdiction debate: Analyzing the Federal Circuit's finding of jurisdiction in *Acorda-Therapeutics Inc. v. Mylan Pharms. Inc.* and *Astra-Zeneca AB v. Mylan Pharms. Inc.*, Reviewing the District Courts' decisions in these cases. Studying the significance of the Federal Circuit's dissent and understanding the significance of the Supreme Court's denial of certiorari in *Mylan* in light of the Court's grant of certiorari in *TC Heartland LLC v. Kraft Food Brands Group LLC*.

### **1645 - 1730 : Session XII**

Discussion about recent changes in Patent Prosecution and Litigation practices in India.



# PROGRAMME OUTLINE

## [Europe, Brazil and Japan Scenario]

### **0930 - 1100 : Session - I**

Pharmaceutical lifecycle management strategies in 2017. Studying a case of pregabalin in Europe. Status of the case in various member states of EU. Dilemma of Swiss type claims: who infringes Swiss type claims? Preliminary Injunctions: How to protect your patent portfolio. The scope of the SPC Regulations. Second Medical Use Patent and Cross label infringement. Prosecution strategies during patent litigation. Unified Patent Court: Current state of affairs and the expected implications on future patent litigation. Identifying the effects of Brexit on the Protection and Enforcement of IP Rights.

### **1100 - 1115 : Tea Break**

### **1115 - 1215 : Session - II**

Brazilian Patent System Update: Brief overview of patent prosecution and enforcement in Brazil. Recent developments in Brazil's patent system including shifts in management, major policy changes, the new pharmaceutical production agreement with India and what is to be expected going forward. Insights as to how to navigate potential challenges. Update on expedition of Patent Prosecution in Brazil.

### **1215 - 1330 : Session - III**

Discussion on the latest Japan Supreme Court judgments and Grand Panel IP High court judgments in the pharmaceutical area: (i) Patent Term Extension, JPO v. Genentech and Debiopharm International v. Towa Pharmaceutical. (ii) Doctrine of Equivalents, DKSH Japan et al v. Chugai Pharmaceutical (iii) Product-by- Process claims, Teva v. Kyowa Hakko Kirin, and Teva v. Tohri

### **1330 - 1430 : Networking Lunch**

### **1430 - 1545 : Session - IV**

A European overview of present status of biosimilars. Current market analysis. Latest developments in strategies to bring biosimilars to the market. Overview of current IP laws in biosimilars and developments in patent expiry. How to launch a case against a biosimilar company? A look at the latest biosimilar litigation cases from the UK. Case Study of Abbvie vs Fujifilm - what this might mean for future litigation cases?

### **1545 - 1600 : Tea Break**

### **1600 - 1700 : Session V**

Update on new guidelines in Brazil involving examination of pharmaceutical patent applications. Brief discussion on decisions issued by the federal courts in Brazil against the Brazilian Food and Drug Agency (ANVISA) involving the prior approval of pharmaceutical patent applications Update on the enforcement of the new OTC Drug Guidelines in Brazil. Update on compulsory licensing (CL) of pharmaceutical patents in Brazil. CL procedure under Brazilian legal framework. Review of recent examples of CL in Brazil.



## ABOUT THE ORGANIZERS

### **KHURANA & KHURANA, ADVOCATES AND IP ATTORNEYS**

Khurana & Khurana, Advocates and IP Attorneys (K&K) is more than a full service Intellectual Property and Commercial Law firm. K&K was formed in the year 2007 with a very firm focus of providing end-to-end IP Prosecution/Litigation and Commercial Law services in a manner that is Corporate centric and follows stringent delivery practices that are consistent and are above defined quality standards. K&K works closely with its sister concern IIPRD, both of which supplement each other in order to provide end-to-end IP Legal and Commercialization/Licensing services to over 3000 Corporates. K&K is a team of over 100 professionals spread across 6 Offices in India, and has strong rankings from Legal 500, MIP, IAM, Chambers, Asia IP, among others. Our team of IP Attorneys/Practitioners, having high level of technical and legal competence, gives us the right competitive edge and positioning, as a law firm focused on creating immense IP value for our clients. K&K through its experienced and qualified team of Attorneys/Practitioners, across Technology and Legal Domains, gives a rare synergy of legal opinion, out-of-box thinking for protection of ideas/IP's and entrepreneurial spirits to its client base. K&K earnestly believes that success comes only when one has a long term perspective and this is why we concentrate on building long term relationships through high level of client orientation.

### **IIPRD**

IIPRD is a premier IP Consulting and Licensing Firm with a diversified business practice providing services in the domain of Commercialization, Valuation, Licensing, Transfer of Technology and Due-Diligence of Intellectual Property Assets along with providing complete IP and Patent Analytics, Transactional, and Litigation Support Services to Indian and International Corporate, Licensing Firms and Global Law Houses. IIPRD has been established precisely to assist the business houses in strategizing their growth by leveraging their IPR's through effective Creation, Promotion, Protection, and Commercialization of IP. IIPRD has a legacy of over fifteen years of existence, and is among the first Indian IP Firms to have core focus on Commercialization, Technology Transfer, and Licensing. IIPRD as strong team of over 100 professionals focus in complete Patent Support and Technology Consulting Matters ranging from conducting all types of Patent Searches, Research and Analytics, Preparation/Prosecution Support, Landscape Analysis, and Claim Charts/Infringement Analysis/Litigation Support.

### **SUGHRUE MION**

Sughrue Mion is one of the world's leading intellectual property law firms managing traditional and non-traditional intellectual property rights, for about five decades, with a wide range of clients around the world. Sughrue's Pharmaceuticals, Biotechnology, Chemical attorneys are trained in technical disciplines that include molecular and cellular biology, biophysics, pharmaceuticals, chemistry, immunology, virology, genetics and agriculture biotechnology. Their experts are particularly well versed in drafting claims to ensure the broadest possible coverage and have a long established expertise in handling patent interference proceedings that may be critical to determining basic patent rights in new areas of biotechnological and pharmaceutical industries. Sughrue Mion handles a wide range of IP litigation matters for clients around the world, and when it comes to serving their clients, they go beyond traditional boundaries, advocating innovative theories and redefining the frontiers of law as they apply to creativity and invention.



## ABOUT THE ORGANIZERS

### **HAMM & WITTKOPP**

A German based IP Law firm, as a team of chemists and biochemists with many years of experience, Hamm & Wittkopp represents its clients in all areas of intellectual property. A major focus of our activities lies in the fields of chemistry and pharmaceuticals – with particular emphasis on generic pharmaceuticals and biosimilars. We offer a comprehensive service of the highest level, from analyzing and clarifying the IP situation, for example via oppositions and nullity actions against troublesome patents, to securing your own innovations via patent applications and defending your interests in litigation proceedings. Our structure allows us to provide tailor-made support in all patent and trademark matters, whereby we are able to act flexibly and efficiently, whilst adapting to the specific needs of each individual case.

### **MURTA GOYANES**

Murta Goyanes is an intellectual property law firm relying on partners with over 30 years of experience and a team of recognized credibility. All partners hold Masters degrees from internationally renowned universities and most associates have taken postgraduate certification. Acting in more than 150 countries through local agents, the firm has extensive experience in portfolio management and prosecution, as well as IP consultancy and enforcement actions. Our practice is distinguished by a philosophy in which every case is unique. This translates into better client handling and timely delivery of services with outstanding technical excellence.

### **SAKAMOTO AND PARTNERS**

Sakamoto and Partners employs several former Examiners and Appeal Examiners from the Japan Patent Office. Our staff brings a plethora of experience in examining Japanese patent applications and are highly knowledgeable with regard to the Japanese Patent Office examination procedures. In addition, our office not only aides in the acquisition of intellectual property rights, but also helps litigate in the event that our client's rights are infringed. We also strive to ensure that our clients are granted intellectual property rights to the fullest extent possible. Sakamoto and Partners has a highly specialized search team for patents, designs, and trademarks at our firm. Most patent firms in Japan do not employ specialized search teams to aid their clients like we do. Our experience and skilled search staff can conduct patent, design, and trademark searches with higher accuracy in a variety of technical fields. Sakamoto and Partners also specializes in patent invalidation searches, and as part of the invalidation searches, we monitor, oppose, and invalidate third-party proceedings, as necessary.





## ABOUT THE FACULTY



### **Mr. Chid Iyer**

Chid received a B.Tech in Chemical Engineering from IIT, Bombay in 1984, MS in Chemical Engineering from University of Akron and MS in Computer Science from the University of Tennessee Space Institute. He received his JD from Georgetown University in 1997. Chid is a partner of International Law Firm of Sughrue Mion and is involved in all aspects of patent practice including litigation, prosecution and client counselling in a variety of technologies with focus on chemical and pharmaceutical. Chid has prepared and prosecuted over 100 applications for a leading research laboratory.



### **Mr. Michael R. Dzwonczyk**

Michael is a partner at Sughrue Mion and has about 20 years of experience in successfully representing multinational companies in patent litigation, including trials and appeals of patent cases. His experience has encompassed technical areas that include pharmaceuticals, recombinantly produced hormones, protein synthesis and expression products, fibers, and medical devices. Michael also counsels clients on intellectual property issues, including validity and infringement of intellectual property rights, licensing and contract matters and Hatch-Waxman issues.



### **Ms. Aiyda Ghahramani**

Ms. Aiyda practices in all areas of intellectual property law with a focus on litigation, rendering opinions on patentability, infringement, and validity, as well as on the prosecution of intellectual property matters. Aiyda is actively involved in connection with preparation of Paragraph IV Notifications under section 505(b), as well as freedom-to-operate, due-diligence and product clearance work, licensing and contract matters, including joint ventures.



### **Mr. Grant Shackelford**

Mr. Shackelford is an associate in the chemical patent and biotechnology / pharmaceutical practice groups, where he maintains an active patent prosecution and litigation practice. Prior to joining Sughrue Mion, Mr. Shackelford taught IP courses for LL.M. and J.D. students and conducted research into patent claim construction. During law school, Mr. Shackelford earned his J.D. from the IIT Chicago-Kent College of Law, where he was a member of the Moot Court Honor Society and Law Review. He received his B.S. in Biochemistry from the University of Missouri-Columbia and M.S. in Chemistry and Chemical Biology from the University of California, San Francisco.



## ABOUT THE FACULTY



### **Ms. Azy S. Kokabi**

Azy S. Kokabi's practice focuses on world-wide procurement, defense and enforcement of patents in the biotechnology and pharmaceutical industries, with focus on prosecution, interference, and litigation motions practice. Kokabi did her post graduation in Biology and JD from George Mason University School of Law. Kokabi has served as counsel in interference proceedings and related matters, before the Board of Patent Appeals and Interferences and the Court of Appeals for the Federal Circuit. Prior to joining Sughrue Mion, Ms. Kokabi also served at the U.S. Patent and Trademark Office as an Examiner.



### **Dr. Alexander Wittkopp**

Alexander is a managing partner at Maiwald Patentanwälte GmbH, based in Hamburg (Germany). He represents his international clients in the areas of German, European, and US intellectual property law, including patent prosecution, oppositions, nullity and infringement proceedings, as well as preparing freedom-to-operate and validity opinions in the field of chemistry, biochemistry, and pharmaceuticals. His experience encompasses the synthesis and morphology of APIs, pharmaceutical compositions of generic drugs and biosimilars, medical and devices, combinations of pharmaceutical agents, and 2 medical uses. Alexander is a qualified German and European Patent Attorney, as well as a US Patent Agent. He practices regularly before the German and European Patent Office, the German District Courts, the German Patent Court, and the Federal Court of Justice.



### **Dr. Toshio Nakamura**

Toshio is a Japanese patent attorney in Sakamoto & Partners. He has 25 years of experience in Patent Prosecution and Litigation, covering general chemistry, pharmaceuticals, biotechnology, patent term extension, etc. He obtained his PhD in chemistry from Tokyo University in 1985. He worked for Sumitomo Pharmaceuticals, Co., Ltd. and Mitsubishi Tanabe Pharma Corporation as a researcher and in the IP department, while he was a trainee at J. A. Kemp in London, U.K. for two years. He joined Sakamoto & Partners in 2016. He made more than 30 publications in chemical field and patent field, and he made around 10 presentations in patent field in India, Europe, Korea and Japan.



## ABOUT THE FACULTY



### **Mr. Fernando Seixas**

Professional experience - Industrial property expert, with emphasis in patents. Worked in renowned law firms, specializing on the field of Intellectual Property. Extensive experience in drafting patentability reports and patent applications, portfolio management, freedom to operate opinions and technical assistance in litigation, in Brazil and abroad, as well as technical advice in product development in view of patent protection. He advises clients in a wide range of industries, including pharmaceuticals, life sciences, biotechnology, and chemicals.



### **Mr. Tarun Khurana**

Tarun has over 14 years of experience in a broad range of Intellectual Property subject matters, and is the Co-Founding Partner and Patent Attorney of Khurana & Khurana, which is among the Leading IP Practices in India with 6 Offices (along with 5 Asian Offices) and over 100 Practitioners. Tarun is among the top 12 Patent Prosecution Practitioners in India as rated by IAM, and has executed numerous assignments related to exercises of Patent Portfolio Creation, Protection, Prosecution, Litigation, Valuation and Commercialization. Tarun has, apart from handling Indian and International Clients for filing and prosecuting cases in India, helped numerous US and European Patent Attorneys in providing Patent Support Services including Patentability Searches, Invalidation Searches, FTO, Infringement Analysis, Patent Preparation and Responding to Office Actions. Tarun has a Bachelors in Computer Science Engineering, a Masters in Software Systems, Bachelors in Law, an MBA from IIM Lucknow, and is in pursuit of his PhD.