RETHINKING PATENT LAW AS AN INCENTIVE TO INNOVATION

International Patent Conference

8–9 OCTOBER 2018

Centre for Innovation
and Technology Transfer Management
of Warsaw University of Technology
Rektorska 4 street, Warsaw

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SOCIETY OF INTELLECTUAL PROPERTY AND COMPETITION LAW

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DAY 1
8th OCTOBER

8.30 Registration

9.30–10.00 **OPENING**

Alicja Adamczak, President of the Patent Office of the Republic of Poland

Krzysztof Lewenstein, Vice-Rektor of the Warsaw University of Technology, Poland

Paweł Podrecki, Chair of the Centre for Legal Studies on New Technologies, Polish Acadamy of Sciences, Poland

10.00–10.30 **INTRODUCTORY LECTURE**

- **The importance of being first**
  Katya Zakharow Assaf, The Hebrew University of Jerusalem, Israel

10.30–11.00 coffee break

11.00–12.30 **PANEL 1. BOUNDARIES OF PATENTABILITY**

Moderator:

Elżbieta Traple, Jagiellonian University, Poland

- **Patenting nature**
  Rochelle Dreyfuss, New York University School of Law, United States
- **Human enhancement and patent law**
  Helena Żakowska-Henzler, The Institute of Law Studies of the Polish Academy of Sciences, Poland
- **Second medical use patents and the boundaries of patent law**
  Tomasz Targosz, Jagiellonian University, Poland

12.30–13.30 lunch

13.30–15.00 **PANEL 2. PATENTS AND TRADE**

Moderator:

Anna Tischner, Jagiellonian University, Poland

- **Trade agreements and their impact on innovation**
  Susy Frankel, Victoria University of Wellington, New Zealand
- **Legal instruments stimulating innovation in pharmaceutical industry. Their importance for the Polish pharma**
  Żaneta Pacud, The Institute of Law Studies of the Polish Academy of Sciences, Poland
- **Patent – a driving force or a costly addition to portfolio? Analysis of non-patent legal factors of marketability in plant biotechnology**
  Tomasz Zimny, The Institute of Law Studies of the Polish Academy of Sciences, Poland

15.00–15.30 coffee break

15.30–17.30 **PANEL 3. ARTIFICIAL INTELLIGENCE & PATENT LAW**

Moderator:

Reto Hilty, Max Planck Institute for Innovation and Competition, Germany

- **Patent protection of computer implemented inventions. Real life examples**
  Jakub Sielewiesiuk, AOMB Intellectual Property, Poland
- **AI patents: is there a need to rethink patent law?**
  Iga Bałos, Andrzej Frycz Modrzewski Krakow University, Poland
- **Artificial Intelligence, novelty and inventive step. What role does AI play in patent law today?**
  Peter Slowinski, Max Planck Institute for Innovation and Competition, Germany
- **Transparency in the patent system. Artificial Intelligence and the disclosure requirement**
  Alfred Früh, University of Zurich, Switzerland

DAY 2
9th OCTOBER

9.00–9.30 **OPENING LECTURE**

- **Are we still encouraged to protect inventions?**
  Krystyna Szczepanowska-Kozłowska, University of Warsaw, Poland

9.30–11.00 **PANEL 4. COMMERCIALISATION OF PATENTS**

Moderator:

Jakub Kępiński, Adam Mickiewicz University in Poznań, Poland

- **'Abuse of rights' and PAEs in European patent litigation: a case law analysis**
  Amandine Léonard, KU Leuven, Belgium
- **Standard Essential Patents. The conflict between open access to standards and the fair reward for innovation**
  Dietrich Kamlah, Taylor Wessing, Germany
- **On the meaning of FRAND**
  Rafał Sikorski, Adam Mickiewicz University in Poznań, Poland

11.00–11.30 coffee break

11.30–13.00 **PANEL 5. PROTECTION OF PLANTS**

Moderator:

Małgorzata Korzycka, University of Warsaw, Poland

- **Rethinking IP protection for plants? Comparing plant breeder's rights, patents and open source**
  Geertrui Van Overwalle, KU Leuven, Belgium
- **The scope of the Farm-Saved Seed under the UPOV acts of 1961 and 1978**
  Juan Antonio Vives-Vallés, University of the Balearic Islands, Spain
- **Rethinking the future of the Breeder's exemption, a culture clash?**
  Ronald Korenstra, AOMB Intellectual Property, The Netherlands

13.00–14.00 lunch

14.00–16.00 PANEL 6. PHARMACEUTICAL INNOVATIONS

Moderator:

Maciej Barczewski, University of Gdańsk, Poland

- **The patentability of genetic therapies: CAR-T and the medical treatment exclusion around the world**
  Jorge Contreras, University of Utah, United States
- **Biosimilars and patent law**
  Marek Świerczyński, Cardinal Stefan Wyszyński University in Warsaw, Poland
- **SPC manufacturing waiver – a tool for increasing competetiveness of generic companies or a weapon detrimental for innovators**
  Justyna Ożegalska-Trybalska, Jagiellonian University, Poland
- **Reconsidering the Bolar exemption: is the legislative framework fit for purpose?**
  Agnieszka Sztoldman, University of Wrocław, Poland

16.00 CLOSING OF THE CONFERENCE

SPEAKERS AND PANELLISTS

DAY 1. OPENING

Alicja Adamczak

President of the Patent Office of the Republic of Poland. Graduated from Law and Administration Faculty at the University of Warsaw. Doctor of Laws, PhD thesis The Attorney in the Patent Proceedings. Member of the Administrative Council and the Budget and Finance Committee of the European Patent Organisation, member of the Administrative Council of the Visegrad Patent Institute. Former president of the Polish Chamber of Patent Attorneys and president of the National Board of Patent Attorneys. Patent attorney, legal advisor and Assistant Professor at the Kielce University of Technology. Long-time editor-in-chief of a quarterly journal Rzecznik patentowy and of scientific journals – series of Innovation and intellectual property protection. Author of many initiatives aimed at promotion of the importance of intellectual property and innovation, promotion of Polish achievements worldwide and of knowledge transfer from universities to industry as well as aimed at education of children, youth and academics. Initiator i.a. of series of symposia Industrial property in innovative economy in Cracow and international conferences Innovation and creativity of women in Warsaw as well as competitions for the best scientific work, information in media and short film to promote the protection of intellectual property. Initiator of Polish celebrations of the World Intellectual Property Day. Instructor of the Polish Scouting and Guiding Association.

Krzysztof Lewenstein

Vice-rector for Academic Affairs at Warsaw University of Technology, university lecturer. Earned his postdoctoral degree (habilitation) in 2003 and two years later he was appointed Associate Professor at the Warsaw University of Technology. His research interests focus on computer-aided medical diagnostics with particular emphasis on artificial intelligence techniques. Prof. Lewenstein was involved in the assessment of the diagnostic power of methods for detection of coronary heart disease, detection of alcohol addiction based on sleep study tests (polysomnogram), screening of myocardial insufficiency according to the original test method, 'artificial pancreas' algorithms for diabetics and, finally, exposimeters for exposure to the effect of electromagnetic fields. Lecturer in electronics, the basics of television technology and artificial intelligence. He has been a master's thesis advisor for over 40 students, authored about 50 scientific publications and published over 60 conference communications. Holder of 7 patents. He reviewed 8 Ph.D. dissertations and many scientific and conference articles. He chaired and participated in the organizational and scientific committees of conferences both at national and international level. Member of the Committee for Medical Physics, Radiobiology and Diagnostic Imaging of Polish Academy of Science. From the beginning of the nineties, in parallel to his scientific activity, Prof. Lewenstein continues to be engaged in the management of the Department. Between 1991 and 1996, he acted as the Vice Dean for Student and General Affairs, then from 1996 to 2002, he was the dean's Plenipotentiary for Investment and Budget. Member of the Senate of the Warsaw University of Technology since 2005, Prof. Lewenstein has participated in the work of a number of committees (financial and investment ones) and since 2008 he has been a chairman of the Senate Didactic Committee. Laureate of the Minister's Award and the Rector of the Warsaw University of Technology. Decorated with the Golden Cross of Merit.

Paweł Podrecki

Professor at the Institute of Law Studies at the Polish Academy of Sciences. Chair of the Centre for Legal Studies on New Technologies. Paweł Podrecki is a member of the Competition Law Association and of the Industrial Property Law Association, and an arbitrator for the Court of Arbitration for Internet Domains. He also held the function of arbitrator at the Copyright Commission and the Court of Arbitration of the Polish Chamber of Commerce in Warsaw. He participates in drafting legislation and prepares expert opinions for the Polish Sejm and Senate. He worked with the Civil Law Codification Commission. At the law firm, he supervises the work of the Industrial Property Law, the Competition and Consumer Protection Law, the Advertising and Sales Promotion Law, and the Life Sciences teams. Paweł Podrecki combines the practice of law with academic work. He gives lectures and seminars on civil law, industrial property law, competition protection law, and unfair competition law at the Jagiellonian University. He is also a lecturer to postgraduate students attending the Jagiellonian University and the Polish Academy of Sciences, and to trainee attorneys-at-law

and patent attorneys. Paweł Podrecki has been repeatedly recommended in Polish and international rankings of lawyers specialising in intellectual property law and competition law (including Chambers Europe, Chambers Global, WTR1000, Legal 500, Rzeczpospolita). Paweł Podrecki is the author of numerous publications on intellectual property law and competition law as well as European law issues. He is the editor of the first, and the largest, IT publication "Prawo Internetu" (The Law of the Internet). His monographs include: "Porozumienia monopolistyczne i ich cywilnoprawne skutki" (Monopolistic Agreements and Their Implications in Civil Law) and Środki ochrony praw własności intelektualnej (Means of protecting intellectual property rights). He is a co-author of many chapters in the Private Law System in the volumes on Competition law and Industrial property law.

INTRODUCTORY LECTURE

Katya Zakharov-Assaf

Katya Assaf-Zakharov studied law at the Hebrew University of Jerusalem (LL.B. and LL.M.), and wrote her Ph.D. at the University of Munich (LMU), Germany, working as a scholar of the Max Planck Institute for Intellectual Property. She is now an assistant professor at the Law Faculty of the Hebrew University and a member of the DAAD Center for German Studies. Her research focuses on Intellectual Property, especially on its social, cultural, philosophical and economic aspects. A significant part of her writings critically analyze consumer culture, brand fetishism, and capitalist ideology in different legal contexts. She is also interested in comparative law, particularly in comparing German and US-American legal regulations and tracing the cultural and philosophic roots of the different legal perceptions.

The importance of being first

This paper considers the right to be acknowledged as the first inventor of a new technology. Technological inventions usually result from accumulative research and development, conducted by different people over decades and centuries. Moreover, sometimes several people arrive at the same invention almost simultaneously. Nevertheless, only one person is usually perceived as the „inventor," and gets all the credit and honor associated with the invention. Hence, the right to be considered as the first inventor can have profound significance for one's professional reputation and career.

This paper focuses on the legal systems of Germany and the United States of America. These systems have developed in substantially different philosophical and cultural climates. Specifically, while the German legal system has been deeply influenced by Kantian and Hegelian thought, the US-American legal system has been inspired by the liberal ideas of John Locke, Adam Smith and others. These two schools of philosophical thought have different perspectives on the relationship between personal identity and work; while the German tradition emphasizes the deeply personal relation between individuals and their work, the Anglo-Saxon approach is, as a general rule, more instrumentalist and utilitarian.

One way in which these differences express themselves is the different ways in which the right to be acknowledged as the first inventor is regulated. This right is deeply connected with one's identity as a professional, whether an engineer, technician, or scientist. On the other hand, this right does not necessarily have pecuniary significance. Hence, the protection of the right to be considered as the first inventor allows a glimpse into the different visions of identity and work found in these legal systems.

This paper examines to what extent German and US-American legal systems recognize and protect the right to be perceived as the first inventor. It focuses on different aspects of this right, in the framework of patent law and beyond. The paper demonstrates that the two legal systems indeed differ profoundly in the ways they perceive and protect the right to be considered as the first inventor. True to its visions on professional dignity, German law carefully protects this right, independently from any pecuniary interests. In contrast, American law grants a remarkably weak protection to the right to be considered as the first inventor, focusing primarily on the monetary aspects of this right. Hence, one can here discover different visions of the role of individuals in society, and specifically of the role of individuals as creators and not just consumers. What is at stake here is the question of whether or not questions of honor, dignity, and symbolic property, above and beyond material benefits, are recognized as playing a role in the economic system.

PANEL 1. BOUNDARIES OF PATENTABILITY

Moderator

Elżbieta Traple

Elżbieta Traple is a senior partner and co-founder of the law firm Traple Konarski Podrecki i Wspólnicy. She is a researcher at the Chair of Civil Law at the Jagiellonian University. Her areas of interest include civil law and intellectual property law. Her academic interests also include unfair competition law, industrial property law, and pharmaceutical law. She advises Polish and foreign companies and entities from the public sector. For more than 10 years, Elżbieta Traple has been the President of the Court of Arbitration at the Chamber of Commerce and Industry in Krakow. She is an arbitrator of the Court of Arbitration of the Polish Chamber of Commerce in Warsaw. She also performed as an arbitrator of the Copyright Commission of the Ministry of Culture and National Heritage. Elżbieta Traple participates in drafting legislation and she is an expert preparing opinions for the Polish Sejm and Senate. She is engaged in the work of international scientific groups dedicated to the creation of model solutions in the field of copyright law and industrial property law. She works with international law organisations and is a member of Deutsches Anwaltsinstitut in Bochum. In the years 1986-1987, 1990 and 1996, she conducted research at the Max Planck Institute in Munich as visiting professor. In the run-up to Poland's accession to the European Union, Elżbieta Traple participated in the work on harmonising copyright law and industrial property law in a group of experts appointed by the European Commission. She has been repeatedly recommended in Polish and international rankings of lawyers specialising in intellectual property law (including Chambers Europe, Chambers Global, Legal 500, Rzeczpospolita). She is the author of numerous publications, including Komentarz do Ustawy o prawie autorskim i prawach pokrewnych (Commentary to the Act on Copyright and Related Rights) (co-author) and System prawa prywatnego – prawo autorskie (Private Law System – Copyright Law) (co-author), the author of the monograph Umowy o eksploatację utworów w prawie polskim (Agreements on the Use of Pieces of Work in Polish Law), the editor and co-author of the publication Prawo reklamy i promocji (Advertising and Sales Promotion Law). She is also the co-author of Prawo farmaceutyczne – zagadnienia regulacyjne i cywilnoprawne (Pharmaceutical Law – Regulatory and Civil Law Issues) and System prawa prywatnego (Private Law System) – a volume devoted to industrial property.

Rochelle C. Dreyfuss

Rochelle C. Dreyfuss is the Pauline Newman Professor of Law at New York University School of Law and co-Director of its Engelberg Center on Innovation Law and Policy. Dreyfuss holds B.A. and M.S. degrees in Chemistry. A research chemist before entering Columbia University School of Law, she served as Articles and Book Review Editor of the Law Review. She clerked for U.S. Court of Appeals for the Second Circuit Chief Judge Wilfred Feinberg and for U.S. Supreme Court Chief Justice Warren E. Burger. She is a member of the American Law Institute and was a co-Reporter for its Project on Intellectual Property: Principles Governing Jurisdiction, Choice of Law, and Judgments in Transnational Disputes. She was a consultant to the Federal Courts Study Committee, to the Presidential Commission on Catastrophic Nuclear Accidents, and to the Federal Trade Commission and served on the Secretary of Health and Human Services' Advisory Committee on Genetics, Health, and Society. She was also a member of the National Academies Committees on Intellectual Property in Genomic and Protein Research and Innovation, on Intellectual Property Rights in the Knowledge-Based Economy, and on Science, Technology, and Law. She has previously visited at the University of Chicago, Oxford University, the National University of Singapore, the University of Washington, and Santa Clara University. Her writings include A Neofederalist Vision of TRIPS: Building a Resilient International Intellectual Property System (Oxford University Press 2012) (with Graeme Dinwoodie) and Balancing Wealth and Health: The Battle over Intellectual Property and Access to Medicines in Latin America (Oxford University Press 2014) (edited and partially co-written with César Rodríguez-Garavito).

Patenting nature

This presentation will examine the Myriad decisions in the United States and Australia (Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013) and D'Arcy v Myriad Genetics, Inc [2015] HCA 35). Both bar patents on naturally occurring products—specifically, on isolated genes. These decisions leave many open questions on the patentability of products and processes that duplicate (or come close to duplicating) material found in nature. They release material for free use by researchers and for patient care. However, they also endanger the future of privately-supported research in the

life sciences. The two decisions are, however, not identical and lower courts have applied them differently. The presentation will discuss the advantages of the Australian approach and why it deals more successfully with dual-use technologies (inventions that are simultaneously research inputs and commercial outputs).

Helena Żakowska-Henzler

The Institute of Law Studies of the Polish Academy of Sciences – the head of the department of Polish and European industrial property law; an author of publications on industrial property rights, in particular patent protection – justification and ethical aspects of such protection, as well as on issues specific to patents in the field of biotechnology and medicine.

Human enhancement and patent law

The concept of human enhancement in its broad sense refers to all interventions aimed at improving the functioning of human body or brain, both to eliminate disease-related deficiencies and to improve their abilities beyond what is necessary to sustain health or cure the body. The latter issue raises great interest and provokes significant controversy. For some people, this is a devilish idea that threatens to destroy the humankind, for others it's a wonderful and promising breakthrough that can make people physically perfect and mentally happy. Since the means to enhance humans are multiple and diverse, this dispute encompasses a great variety of issues and offers different conclusions.

My paper will focus only on one specific aspect of the human enhancement – human enhancement in the context of patent law. Generally, it will inquire whether the various concerns associated with enhancing humans should be reflected in the rules of patent protection. Specifically, it will focus on two questions.

1. *Is there de lege lata basis for clear rules to assess the patentability of such inventions? Or, alternatively, should the legal rules in this field be context-specific, following the example of the current provisions governing biotechnological inventions? This dilemma concerns i.a. a) the distinction between methods aimed at human enhancement and non-patentable methods of medical treatment; b) assessment of compatibility of these inventions (its exploitation) with public order and morality.*
2. *Should patent law set specific rules to allow access to patented inventions aimed at human enhancement, limiting the exclusivity of patent rights? This question arises from the potential social consequences of exclusivity over this kind of inventions. Exclusive rights in methods of human enhancements may lead to a new social stratification – emergence of a higher class of enhanced people and a lower class of unenhanced ones. New means of human enhancement may thus become a determining factor for the people's social position. According to current principles of patent law, shaping these classes would be at least partly left to the discretion of the respective patent owners.*

All these questions are closely connected with the search for an optimal model of distribution of human enhancement and the role of the patent system in this context.

Tomasz Targosz

Tomasz specialises in intellectual property law, in particular copyright and related rights as well as patent law, and, furthermore, in unfair competition, antitrust, and general civil law. He is the author and co-author of academic publications in the field of civil and commercial law, copyright law, new technologies law, and of many articles in law journals. He has been a speaker at conferences and training courses in Poland and abroad. Tomasz Targosz, having graduated from the Faculty of Law and Administration at the Jagiellonian University in Krakow, teaches at the Chair of Intellectual Property Law at his alma mater. He is a practicing attorney.

Second medical use patents and the boundaries of patent law

Second medical use patents pose several unique questions about the scope of protection IP rights can provide and the ability of those rights to meet the demands of the interested stakeholders, without losing the public interest out of sight. Enforcement of such patents is either weak or excessive. It must be often accompanied by measures rather unusual for traditional patent law. It is also the area where direct and indirect infringements are most difficult to delineate, which is of course especially important for countries that (like Poland) have not yet introduced indirect patent infringement into their patent laws. Finally, this is perhaps the place where the perspective of fundamental rights, so prominent in recent copyright decisions, could start to really matter in patent law as well. The presentation will focus on how and under what conditions second medical use patents can be infringed and where the boundaries for effective but proportional enforcement measures should be drawn.

PANEL 2. PATENTS AND TRADE

Moderator

Anna Tischner

Anna Tischner (dr hab.) is an associate professor at the Intellectual Property Law Chair of the Jagiellonian University in Cracow, Poland. Anna's main field of academic interest is: industrial property and unfair competition law. She is especially interested in European design law. Her publications include two monographs (in Polish): „Civil liability for trade mark infringement" (WoltersKluwer 2008) and „Cumulative protection of designs in the intellectual property law" (C.H. Beck 2015), numerous chapters, articles and selected parts of a commentary on the Polish Industrial Property Act (Beck 2014). She is also the co-editor of the Jagiellonian University Intellectual Property Law Review, peer-reviewer of the International Journal of Intellectual Property and Competition Law (IIC). Anna has been a member of ATRIP since 2009 and ATRIP ExCo member for the term 2016-2019. She is also a member of the External Advisory Board of EIPIN Innovation Society programme.

Susy Frankel

Susy Frankel is a Professor of Law, holds the Chair in Intellectual Property and International Trade and is Director of the New Zealand Centre of International Economic Law, at Victoria University of Wellington, New Zealand. She was the President of the International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP) from 2015-2017, and with Dr Anna Tischner, of the Jagiellonian University, hosted ATRIP in Krakow in 2016. Since 2008 Professor Frankel has been Chair of the Copyright Tribunal (NZ). She is a member of the editorial boards of the Journal of World Intellectual Property Law and the Queen Mary Journal of Intellectual Property. She teaches copyright, trade marks, patents, international intellectual property and international trade law. Her scholarship focuses on international intellectual property and its nexus with international trade; particularly treaty interpretation and the protection of indigenous peoples' knowledge and innovation.

Trade agreements and their impact on innovation

The TRIPS Agreement provided a platform of substantive minimum standards for patent law that was much more detailed than any previous agreement. TRIPS also retained much flexibility, including around patentability criteria. With no definition of novelty, inventive step and utility in the Agreement, World Trade Organization members can apply and develop their own definitions, provided that their laws comply with TRIPS. The position of those who wanted flexible global standards are, in part, reflected in the general provisions of TRIPS which provide, among other things, that intellectual property protection takes into account the position of both users and producers and that countries may regulate for public health. While TRIPS created a subject matter and rights platform, many differences remain in national patent law around the details of that platform, and other rules, such as patent term and the patent law relationship with data exclusivity and health and safety regulation. Some seek to eliminate these differences and others suggest diversity is an important reflection of the purposes of patent law, including innovation and development. In this presentation I will discuss examples from multilateral, regional, plurilateral and bi-lateral trade agreements and negotiations that post-date TRIPS and how they both directly and indirectly impact global patent and data regulatory standards and consequently Poland's place in the world patent order.

Żaneta Pacud

Żaneta Pacud graduated in law and European studies at Adam Mickiewicz University in Poznan. She obtained her PhD in 2012 at the Jagiellonian University in Cracow. For her dissertation, devoted to patent protection of medicinal products, she was awarded by Ministry of Science and Higher Education in the contest for the best doctoral thesis in the field of intellectual property. She coordinated an international research project "Innovation Expert System" at the Chair of Intellectual Property of the Jagiellonian University and was lecturer there. She was granted a scholarship at the Max-Planck-Institute for Innovation and Competition in Munich twice. At present she is a post-doctoral researcher at the Institute of Law Studies at the Polish Academy of Sciences in Warsaw and an associate professor in the Chair of Civil Law at the University of Łódź. Her interests focus on industrial property, especially on patent law. Currently she conducts studies on non-patent protection for pharmaceuticals and also participates in a research project devoted to biotechnological inventions in the context of fundamental rights. She is a practising attorney-at-law.

Legal instruments stimulating innovation in pharmaceutical industry. Their importance for the Polish pharma

Pharmaceutical innovations differ substantially from other kinds of pioneering products and services.

First, pharmaceutical market is one of the most regulated sectors to date. Trade in medicinal products is dependent on fulfilment of high requirements concerning their safety and efficacy, these being verified in a scrutinised marketing authorisation procedure. As a result, development of a new drug is both time-consuming and extraordinarily expensive. Secondly, pharmaceutical R&D involves highly sensitive issue of clinical testing on human beings and a common belief of necessity to avoid duplicative testing. Thirdly, a medicinal product, once commercialised, may be copied easily and produced at a very low cost.

For these reasons the pharmaceutical industry – as no other one – is divided into innovative and generic sectors. Whereas availability of a strong legal protection for medicinal products is perceived as crucial to the research based industry, the generic sector demands fair rules of access to the market. Patients and public health institutions expect both – new, highly innovative products on the one hand and availability of affordable drugs on the other. The legal instruments designed for protection of medicinal products shall balance the interests at stake and keep pace with the technological changes in this industry.

My presentation is divided into two parts. The first one aims at describing the specificity of patent and non-patent protection for pharmaceuticals, comparing their functions and meaning for both sectors of the industry. It serves as a background for the second part, presenting results of a WIPO – PPO research project concerning innovation in the Polish health sector. The aim of this project was – i.a. to assess what is the impact of patents and other intellectual property rights on the innovation in the domestic pharmaceutical industry. The results of the project are interesting for the sake of a better understanding of the role that patents, SPC and data exclusivity play in an emerging economy and in a relatively young pharmaceutical industry.

Tomasz Zimny

Dr Tomasz Zimny works at the Institute of Law Studies of Polish Academy of Sciences. Apart from a PhD in law he has a master's degree in philosophy and an advanced certificate in bioethics. He is interested in processes that happen at the meeting point of normative systems and scientific research, in particular in the field of life sciences. While patent law remains his main area of interest, he also published papers on biosafety, legislation regarding use of genetically modified organisms, and bioethics. Dr Zimny teaches Intellectual Property Law to biotechnology and car engineering students at the Warsaw University of Technology, he is also an attorney at law.

Patent – a driving force or a costly addition to portfolio? Analysis of non-patent legal factors of marketability in plant biotechnology

Patents are often considered to be driving forces for innovative activity. The incentives they create are called upon as reasons for the existence of the whole patent system. Yet they remain only one of the factors that influence investments in research and development activities. A patent for a product that cannot be sold for lack of demand or other reasons (such as legal restrictions), is a source of loss, due to the costs connected with its obtaining and maintenance. Hence even a favourable patent policy can prove insufficient to create a friendly environment for investments in certain areas. This seems to be the case for innovation in plant biotechnology, in particular with regard to genetically modified organisms (GMOs) and plants derived through some new plant breeding techniques.

Currently the European Union has one of the strictest regulations regarding authorisation of genetically engineered plants for cultivation. So far only one modification (the MON 810 Maize) has been placed on the market. Furthermore, genetically engineered products need to be labelled as such, which combined with general negative attitudes towards them limits their eventual use to animal feed form most practical reasons (though they are used extensively in this area). Another factor limiting the use of novel methods in plant breeding is the fact that as of the entry into force of the 2015/412/EU Directive member states are essentially free to prohibit cultivation of GM plants on their territories even if such plants were authorised. The abovementioned factors limit the usage of genetic engineering in some areas of biotechnology to basic research mostly, as many possible products are for all practical reasons unmarketable.

The described phenomenon is also influenced by the fact that the definition of GMO in the Directive 2001/18/EC is quite vague, making it difficult do decide if some of newer techniques employed in plant breeding (e.g involving precise mutagenesis) are to be treated as leading to the creation of GMOs or not. Recent jurisprudence seems to suggest that the definition should be interpreted broadly, further limiting the choice of methods to be used in the breeding process.

The abovementioned factors cause a situation, in which while many innovations in plant biotechnology would be patentable, easily escaping the essentially biological processes exclusion through the employment of technical steps in their

development, it is economically unjustified to invest in them. These innovations (e. g. novel kinds of food and feed) are present on the European market, but mostly through imports from other areas .

In order to verify that even a favourable patent policy can prove insufficient to create a friendly environment for investments in certain areas, I contrast the patent law provisions for the patentability of plants and methods of their modification, with the legal framework that regulates the implementation of such inventions, in particular EU law regarding the common catalogue of plant varieties, marketing of genetically modified organisms and introduction of novel food.

PANEL 3. ARTIFICIAL INTELLIGENCE & PATENT LAW

Moderator

Reto Hilty

Study of mechanical engineering at the Swiss Federal Institute of Technology Zurich (ETH Zurich; first intermediate diploma); Study of law University of Zurich School of Law, doctorate Zurich (1989); Head of Department and Member of Board of Directors at Swiss Federal Institute of Intellectual Property, Berne (1994-1997); Post-doctoral degree (habilitation) in civil, intellectual property, competition and media law University of Zurich (2000); Full Professor for technology and information law at Swiss Federal Institute of Technology Zurich (ETH Zurich, 2000-2002); Director and Scientific Member at the Max Planck Institute for Innovation and Competition (since 2002); Full Professor of law at University of Zurich (part time, since 2002), Honorary Professor of law at Ludwig Maximilians University of Munich (since 2002); Honorary Professor at the Zhongnan University of Economics and Law, Wuhan, P.R. China (since 2007); Honorary Professor at the Xiamen University, P.R. China (since 2009); Consultant Professor at the Huazhong University of Science and Technology, Wuhan, P.R. China (since 2009); Honorary Professor at the Tongji University, Shanghai, P.R. China (since 2015); Guest Professor and Member of Academic Committee der Renmin University of China, Intellectual Property Academy, Peking, P.R. China (since 2015).

Jakub Sielewiesiuk

PhD, patent attorney, partner & President of the Board of Directors Patent attorney in AOMB law firm.

Patent protection of computer implemented inventions. Real life examples

There is apparent business need for effective protection of computer implemented inventions (CII). The presentation will briefly address shortages of copyright protection in this respect (concluding superiority of patent protection) and will then focus on examples of CII taken from practice of the speaker (a Polish and European patent attorney in private practice). The examples will illustrate diversity of fields in which CII are made, each accompanied with a "true story" of particular patent application before the Polish patent office (PPO) or European patent office (EPO). This should allow the audience to appreciate different types of relationship between the "software" and the "hardware" in such inventions, which is some cases is really sophisticated. Also, the practice of the PPO and the EPO will become apparent based on the "true stories".

Iga Bałos

Iga Bałos earned Ph.D. degree in law in 2015. Her thesis concerned arbitration in patent disputes (First Prize for the best doctoral thesis in the field of intellectual property law in the contest organized by The Patent Office of the Republic of Poland). She is an Assistant Professor at AFM Krakow University, where she teaches patent law, and of counsel in one of the intellectual property law offices in Krakow. She is the author of several publications on IPRs and unfair competition. She gave talks during 32nd Chaos Community Congress in Hamburg, organized by Europe's largest association of hackers ("Software and business methods patents: call for action" with B. Henrion) and 1st OverDrive Conference at Escola Politecnica Superior, Girona ("What's law got to do with it: hacking and autonomous cars"). She has been engaged in software patent debate since 2009 (e.g. Amicus Curiae in case G 3/08 before EPO enlarged board of appeal; expert comments for nationwide radio and press).

AI patents: is there a need to rethink patent law?

AI is everywhere. It stimulates imagination of writers, filmmakers and lawmakers as well. The European Parliament has recently decided in its resolution that "(…) the most sophisticated autonomous robots could be established as having the status of electronic persons". AI seems to be perceived by the public as another word for innovation. There are three issues. I would like to address in this paper:

1) Are all AI related inventions truly innovative?
2) Do AI patents encourage innovation?
3) Do AI patents require a rethinking of patent law?

Peter Slowinski

Peter Slowinski is a Junior Research Fellow at the Max Planck Institute for Innovation and Competition in Munich. He is admitted as attorney-at-law (Rechtsanwalt) in Germany as well as a qualified and certified mediator. He studied law at the University of Passau, the Ludwig Maximilians University Munich, Cardiff University in Wales and Stanford Law School. At Stanford Law School he obtained a Master in the Science of Law (J.S.M.) after researching on alternative dispute resolution and patent law as part of the Stanford Program in International Legal Studies (SPILS). He has given lectures at Stanford Law School and the Munich Intellectual Property Law Center (MIPLC). Until 2016, he practiced as a patent litigator in infringement and nullity proceedings with a global law firm in Munich. In this capacity he represented clients in the Regional and Higher Regional Courts in Germany as well as the German Federal Patent Court and the Federal Supreme Court. His research focuses on patents and dispute resolution. He has published on copyright law and patent law. His doctoral research concerns the appropriate balance in the enforcement of IPRs. Peter Slowinski was involved in a major study on the future of the legal profession at Stanford Law School and the SPC Study of the Max Planck Institute for Innovation and Competition. He is a member of the research group on data driven economies and artificial intelligence at the Max Planck Institute.

Artificial Intelligence, novelty and inventive step. What role does AI play in patent law today?

While the idea of artificial intelligence (AI) is almost as old as computer science itself, the topic as well as the technology have made a substantial development in recent years. The most discussed questions are whether AI will one day be recognized as a creator of a work according to copyright law or as an inventor according to patent law.

However, while the AI that decides to paint, compose or invent by itself for its own reasons may be still far away, it does play a role in the creative and inventive process. At the moment the greatest advantage of AI over the human mind is its capability to process huge amounts of information with high precision. This means that it is primarily searching and combining existent knowledge and building decisions and new knowledge on this. And combining knowledge and drawing new conclusions and/or solutions from it is, after all, the core question of novelty and inventiveness in patent law.

So what does this mean for the law and the guiding concepts of novelty, inventiveness and the person skilled in the art? My paper and presentation takes a closer look at what AI can actually do today and how it is already being used in the innovation cycle. Furthermore, it analyses the concepts that are the foundation of present patent law in Europe as well as the US. Finally, I demonstrate how the use of AI influences these concepts and how it may force us to rethink which steps in the development of new products are in fact innovative from the perspective of present law.

Alfred Früh

Dr Alfred Früh is a postdoctoral researcher at the University of Zurich (UZH) and the managing director of UZH's Center for Information Technology, Society, and Law (ITSL). In his current research, he is investigating the role of transparency within the competition system. His further research interests are in the law of the Digital Society, Data Governance and Intellectual Property as well as Competition Law. Alfred studied law at the University of Zurich. He was a Guest Researcher at the Max Planck Institute for Innovation and Competition in Munich and a Visiting Fellow at the Alexander von Humboldt Institute for Internet and Society (HIIG) in Berlin. His doctoral thesis on the interface of Intellectual Property and Competition Law («Immaterialgüterrechte und der relevante Markt») was funded by the EMPIRIS foundation and awarded the Issekutz price by the University of Zurich's Faculty of Law. After completing his doctoral thesis, Alfred worked, inter alia, with a leading Swiss law firm. Alfred is admitted to the bar in Switzerland. He is a lecturer at UZH and the Private University of Fürstentum Lichtenstein (UFL). He is also a member of various professional associations as well as the Digital Society Initiative (DSI).

Transparency in the patent system. Artificial Intelligence and the disclosure requirement

The widespread application of technologies pertaining to the field of Artificial Intelligence (AI) is about to challenge various aspects of the patent system. Common topics include the inventive capacity of AI, attribution of rights to the machines applying AI, liability issues and how the use of AI shapes the non-obviousness standard.

The presented paper addresses the related – but less obvious – question whether the use of AI has similar profound implications for patent law's disclosure requirement. The disclosure requirement demands from the inventor to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

This provision arguably plays a key role in disclosing inventions to the public (diffusion of innovative knowledge) and has been understood as describing the right holder's quid pro quo performance of a contract with the public, whereby the right holder is rewarded with legal protection for disclosing information that had previously been secret. Some even consider this the main justification for the patent system (contract theory).

However, AI's unique features and possibilities may challenge the disclosure requirement and impede the transparency associated with it in several ways. Two cases merit closer examination: First, I examine the situation in which an invention requires the application of AI techniques and assume that the use of AI is fully disclosed. Considering that the actual workings of neural networks are – even for AI engineers – generally unknown (and that some speak of a ‚black box'), I will examine the argument that the disclosure requirement cannot be met. Second, I consider the case in which a patent is not sufficiently disclosed in the traditional sense, but would meet the disclosure standard if the person skilled in the art were able to resort to AI. Allowing the person skilled in the art to apply AI could result in a flood of applications, whereas prohibiting the person skilled in the art to resort to AI might significantly hamper innovation.

But AI does not only challenge the disclosure requirement. It could also add new meaning to it and increase transparency. After all, machine learning and similar technologies are potentially able to digest the entire ‚universe of prior art'. They could provide a whole new level of inventive capacities – given that prior art is sufficiently disclosed.

DAY 2. OPENING LECTURE

Krystyna Szczepanowska-Kozłowska

Professor Krystyna Szczepanowska specialises in litigation, both in intellectual property law and in business and arbitration disputes, representing clients before the common courts and administrative courts. She also advises clients on non-contentious matters, especially in civil law, intellectual property and new technologies law. Moreover, professor Krystyna Szczepanowska-Kozłowska has been listed as an arbitrator of the Court of Arbitration at the Polish Chamber of Commerce since 2003 and has taken part in numerous international cases as counsel or arbitrator. Professor Krystyna Szczepanowska–Kozłowska is also a member of the Faculty of Law at the University of Warsaw where she heads the Department of Intellectual Property Law and Intangible Assets. She is the author of numerous academic publications.

Are we still encouraged to protect inventions?

The patent system has been heavily criticised recently. It has been stressed by many authors that the current patent system has not supported innovation properly. Specifically, concerns have often been raised that patents hamper further innovation, limiting access to essential knowledge and too broad protection for basic invention can discourage further developments and research. The criticism is also related to changes which were introduced to the patent system, theoretically strengthening patent rights by expanding their coverage and easing their enforcement. Usually, the mentioned trends are used to support the conclusion that we find that the current patent system no longer successfully balances the struggle between patent holders and the third parties operating on the market. However, some deficiencies of the patent system may also raise doubts as to whether is still worth seeking patent protection. The main objective is to discuss whether inventors are really encouraged to patent an invention.

PANEL 4. COMMERCIALISATION OF PATENTS

Moderator

Jakub Kępiński

Jakub Kępiński is an assistant professor at the Adam Mickiewicz University in Poznań, Poland. In his scientific research he focuses on the Intellectual Property Law, in particular on design law and unfair competition law.Jakub Kepinski is an author of a monography about protection of designs (2009) and a co-author of the commentaries on Polish unfair competition law and on Polish civil law. He is also an author of several chapters in monographies and more than 30 articles on IP Law. In 2010 he was granted a Master Degree of Laws (LL.M) in International Business Law at the Central European University in Budapest. He teaches Polish and Erasmus students. He lectured on IP Law abroad [Russia (2012), Spain (2012, 2018), Greece (2013), Finland (2014, 2015) and Cyprus (2017)]. He also takes active part in many scientific conferences in Poland and abroad. He works as a legal advisor in Poznań.

Amandine Léonard

Amandine Léonard obtained her Master of Laws with a specialization in business law (cum laude) in 2012 from the University of Liege. In 2013 she completed the LLM program of the Liege Competition and Innovation Institute (LCII) in European Competition law and Intellectual Property (magna cum laude). Since October 2013, Amandine is a legal researcher at the KU Leuven Centre for IT & IP Law. In January 2015, she obtained a PhD Scholarship from „Flanders Innovation & Entrepreneurship" (VLAIO) to work on the topic of "Abusive patent litigation in Europe – The prohibition of abuse of rights and patent trolls". During her PhD she will investigate patent litigation strategies adopted by patent holders both in the currently spread patent litigation system of Europe, and in the future Unitary Patent Package system. From January to April 2018 Amandine was a visiting researcher at Stanford Law School (US) for which she received an FWO travel grant. Her particular fields of research are: the fundamental rationale and objective of intellectual property laws (patent, copyright and trademark), the approach adopted by the United States and European countries regarding intellectual property laws and their limitations and exceptions, as well as the interface between competition law and intellectual property law.

'Abuse of rights' and PAEs in European patent litigation: a case law analysis

The topic of Patent Assertion Entities (PAEs) in Europe has recently seen an increased interest by the European Commission, the EPO, practitioners as well as academics. Traditionally, it is argued that the fragmented system of litigation in Europe, the differences in national legal systems, the availability of funding for PAEs as well as cultural differences, prevent PAEs from entering the European market. However, recent studies show that PAE activities in Europe have grown.

These activities have created concerns that, similar to the US, PAEs may have opportunities to 'abuse' the current and future patent litigation system in Europe. In 2017, the Support Study for the evaluation of the IP enforcement Directive by the Commission notably mentioned that the topic of Non-Practicing Entities (NPEs) suggests that the tools and remedies available to defendants may have to be reviewed in order to ensure an equilibrium between litigants and avoid abuse of patent rights. Similar concerns have also been shared at the industry level. Additionally, certain characteristics of the (up-coming) Unitary Patent system have been considered as particularly attractive for PAEs and have created a fear that the system may open the door to more strategic assertion in the future.

This presentation focuses on these concerns vis-a-vis NPEs and particularly PAEs and the opportunities they may (or may not) have to 'abuse' the patent litigation system. To assess whether PAEs have engaged in 'abusive practices' in Europe, a review of case law has been conducted. This analysis focuses on 60 entities identified in literature as NPEs and/or PAEs and instances in which courts have considered defenses based on "abuse of rights" or similar national concepts. The outcome of this research will also be put in perspective with the body of rules governing the Unified Patent Court.

Dietrich Kamlah

Dietrich Kamlah is a member of Taylor Wessing's patent group in Munich. Dietrich's expertise includes the representation of clients in national and international patent infringement litigation as well as advice on contractual matters involving patents and technical know-how, such as R&D cooperation agreements. He also works on antitrust related issues in IP cases such as standard essential patents. His clients come from all areas of technology with a special focus on IT and telecoms, pharmaceuticals, medical devices and automotive. Beginning in 2002, Dietrich worked for clients in field of IP law in international law firms. He became partner at Taylor Wessing in 2008. Dietrich studied law at the University of Passau and King's College London. After taking the German bar exam in 2000 he worked as lecturer at the University of Erlangen-Nuremberg where he completed his PhD with a thesis on antitrust law. Dietrich is a member of the following associations: GRUR (German Association for IP and Copyright), LES (Licensing Executives Society) and AIPLA (American Intellectual Property Law Association). He contributed as co-author to a patent law handbook and publishes regularly in the field of patent law.

Standard Essential Patents. The conflict between open access to standards and the fair reward for innovation

Modern telecommunication with fast access to data from almost anywhere has changed the world. It heavily depends on common standards ensuring interoperability between different devices. These standards work on the basis of numerous inventions protected by patents. The balance between open standards and the fair reward for the inventors shall be guaranteed by licenses under FRAND (fair, reasonable and non-discriminatory) terms. What FRAND really means and how it can be implemented in practice, however, is the subject of intense legal battles in courts all over the world and despite years of litigation there is still no commonly accepted solution. With the rise of industry 4.0 and connected cars, the concept of FRAND terms for access to patented standards will become even more important and involve virtually every industry.

In its landmark decision Huawei v. ZTE the European Court of Justice laid out a procedural framework for negotiating FRAND terms. Generally the patentee has to make a license offer to the defendant under FRAND terms, before a standard essential patent can be enforced by injunctive relief. The defendant has to react in a timely and constructive manner and make a counter-offer, if the patentee's initial offer appears unacceptable. In subsequent patent cases, however, national courts applied Huawei v. ZTE in very different ways. While the UK High Court determined the actual FRAND rate for the standard essential patents asserted in the Unwired Planet v. Huawei case after hearing economic experts and reviewing comparable agreements, the German courts still try to avoid the FRAND determination and put the burden on the parties. The Mannheim regional court ruled in Pioneer v. Acer that it will not engage in more than a high level review of FRAND terms, because a full review would be unduly burdensome for the court and endanger the effective enforcement of IP rights. The Düsseldorf regional court initially had a similar approach, but was corrected by the Düsseldorf higher regional court in Sisvel v. Haier. In this case the plaintiff was required to disclose its prior licence agreements in order to ensure that the license terms offered to the defendant were not discriminatory. This opened the way to a meaningful discussion of the plaintiff's license offer and resulted in a dismissal of the action for an injunction, because the plaintiff's license offer was regarded as discriminatory.

Despite these initial rulings a lot of important issues still need clarification and it is open how they will be approached by the courts. The presentation will give you an introduction some of the resolved and open questions on FRAND and how they were approached in different cases.

Rafał Sikorski

Rafał Sikorski is a Professor of Law at the Faculty of Law of the Adam Mickiewicz University in Poznań, Poland. He teaches intellectual property, civil, private international and European Union law. In 2000 he obtained an LL.M. in International Business Transactions from the Central European University in Budapest, Hungary. In 2005 he obtained his Ph.D. from the Adam Mickiewicz University. His major research areas include: patent law, patent remedies, intersection of intellectual property and competition law, standardization and standard essential patents, as well as private ordering in patent law. He has published on patent pools, SEPs and standard-setting, patent remedies, conflicts-of-law rules for IP contracts and IP infringement as well as on copyright law. Professor Sikorski is also an attorney-at-law and a senior partner at SMM Legal, one of the leading Polish law firms. At SMM Legal he heads the IP Department.

On the meaning of FRAND

Commitments to license patents on fair, reasonable and non-discriminatory (FRAND) terms have become central to the operations of significant number of standard-setting organizations. They are perceived to be necessary to ensure that proprietary standards are available to all market participants who wish to implement them in their products. Though majority of FRAND commitments are made within the context of standard development, such commitments are also made outside of that context, principally to draw the attention of various market participants to particular patent protected technologies and to ensure that licensing fees will be kept at the level allowing for their broad use.

FRAND commitments have attracted global attention. There is a growing consistency in the interpretation of FRAND globally by courts and market participants.

The purpose of the presentation is to examine the origins of FRAND commitments, the scope of their application in various industries and last, but definitely not least the meaning of the "fair, reasonable and non-discriminatory". FRAND commitments are strongly linked to antitrust/competition laws. They were present in various forms in the US back in the 1940's and also became widely referred to by the competition authorities in the EU at the end of the 20th century. With the growing importance of standardization, they have also become essential to the success of standard-setting efforts by organizations developing standards.

When uncovering the meaning of FRAND one must consider the purpose of such commitments, namely concerns over patent hold-up or royalty-stacking. With these concerns in mind, FRAND addresses concerns of patent implementers. But, reasonableness and fairness also require that the rationale underlying the patent system, namely to encourage innovation, is also properly considered. The presentation will be an attempt to show how these concerns may be balanced and what interpretational criteria result from such balancing.

PANEL 5. PROTECTION OF PLANTS

Moderator

Małgorzata Korzycka

Affiliated at the Warsaw University, Law and Administration Faculty, Institute of Law and Administration Sciences, Department of Agricultural Law and Food Protection System, Head of the Food Law Section. Author of many publications and scientific opinions in agricultural law, food law and intellectual property rights in agriculture, most notably monographs: on the protection of agricultural property rights (doctoral thesis), exclusive rights to a new plant variety (habilitation thesis honored II Prize by "State and Law" journal Competition) as well as books on food law (the most recent one entitled "Food Law System" together with P. Wojciechowski published in 2017, Wolters Kluwer). Masters and Doctoral Thesis supervisor and reviewer (also for foreign students). Conducts since 2010 course on food law for Erasmus students at the Faculty of Law and Administration, Warsaw University. Participated in the Warsaw University Faculty of Law and Administration Warsaw- Beijing Forum program (lecturing on food law in 2016 and 2017). Judge apprenticeship followed by exam completed successfully. Scientific interests cover Polish and European food and agricultural law, especially: Polish and European agricultural and food law, protection of agricultural property rights, human rights in food law ("right to adequate food"), intellectual property rights in agriculture and food area. Participant in multiple scientific events as a lecturer, conference speaker and panelist (in Europe and USA) including Bloomington, Indiana University (1984-1985; 1995-1997), Viterbo (Italy) IP Erasmus 2011, Global Food Law and Quality (GLFQ) and Wageningen (Food Law Institute (2009-2012). Fulbright Senior Research Grant at the Indiana University (1995-1996), Research Associate at the Ostrom Workshop in Political Theory and Policy Analysis, Indiana University, USA (1983-1985; 1996-1997) cooperated with Vincent and Elinor Ostrom (Nobel Prize winner 2009). Member of various scientific councils and committees, among them: Editorial Board of "European Food and Feed Law Review", Lexxion (since 2006), Editorial Board of "Forum Prawnicze" ("Legal Forum"), European Committee of Agricultural Law (C.E.D.R.), Minister of Agriculture and Rural Development Council for the Food Quality Products.

Geertrui Van Overwalle

At present Geertrui Van Overwalle is professor of Intellectual Property Law at the University of Leuven (Belgium) and the School of Law – Sciences Po (Paris, France). She is also visiting professor at the University of Tilburg (the Netherlands). In her research, Geertrui Van Overwalle has focused on patents, genetics and their impact on access to health. The results of this research have been published in many internationally peer reviewed journals, such as Nature and Science, and in her books Gene Patents and Public Health, (Brussels, Bruylant, 2007) and Gene Patents and Collaborative Licensing Mechanisms. Patent Pools, Clearinghouses, Open Source Models and Liability Regimes (Cambridge University Press, 2009). She continues working on this thread of research, mainly in the domain of agriculture. In her recent scholarly work, Geertrui Van Overwalle also started a new line of research on the legal architectures and the normative implications of open innovation initiatives from a legal, philosophical and economic perspective. In doing so, she explores both firm-centered and community-centered open innovation models in a wide range of technologies, ranging from life sciences, over design to 3D-printing and the Internet of Things. Geertrui Van Overwalle was a member of the Economic and Scientific Advisory Board (ESAB) of the European Patent Office. She was president of the European Policy for Intellectual Property (EPIP) Research Association (2012-2013). Until recently, she was also a member of the national Belgian High Council for Intellectual Property. For many years, she is a member of the Scientific Advisory Board (Fachbeirat) of the Max-Planck-Institute for Innovation and Competition Law (Munich). She contributed as an expert to the Report Policy options for the improvement of the European patent system commissioned by the European Parliament. She has also undertaken research for the European Group on Ethics in Science and New Technologies (EGE) who directly advises the EU President. Furthermore, she was a member of the first European Commission's Expert Group on Biotechnological Inventions. She was a member of the Board of Appeal of the Community Plant Variety Office at Angers.

Rethinking IP protection for plants? Comparing plant breeder's rights, patents and open source

Plant patents have been the subject of considerable debate over the past years. Patent protection for plants resulting from essentially biological processes – notably tomatoes with reduced fruit water content and broccoli with anti-cancer potential – spurred stormy disputes. Patent infringement of plant biotech patents – in particular soybeans – equally fueled a legal battle. In an attempt to come to grips with the complexity and controversy raised in the broccoli/tomato case, the EU Commission issued a Notice on 8 November 2016, resulting in the introduction of a new Rule 28 in the EPC Implementing Regulations in in 2017.

The present paper will first look into the EPO case law relating to the broccoli/tomato case in depth, and examine the impact of the EU Commission initiative on the protection of plants by patents and/or plant breeder's rights. This analysis will be complemented by focusing on two recently emerging trends which trigger new questions: patents for plant traits, and patents for new genome editing techniques. The recent decision of the Court of Justice of 25 July 2018 on CRISPR-Cas in response to a preliminary ruling concerning the interpretation and validity Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and its impact on plant patenting will thereby be investigated.

Secondly, the paper will discuss access to plants and seeds, as this is key in the recent debate on food security and agro-biodiversity. Some scholarsopt for the use of traditional patents, rendering them more accessible via standardized patent clearinghouses. Others propose the use of open source licenses. Yet others, suggest abandoning property rights and forsaking patents or dedicating patents to the public domain. The present paper critically looks at all those approaches.

Juan Antonio Vives-Vallés

Juan Antonio Vives-Valles is an Assistant Lecturer (Assistant Professor hab.) at the University of the Balearic Islands. He holds a B.Eng. in Agronomy (Spanish Dipl.) from the UIB and a M.S. degree (Spanish Lic.) in Agronomy from the University of Lleida (Catalonia), with specializations in Horticulture & Gardening and in Rural Development. A freelance consultor since 2006, in 2008 he decided to combine his job with his passion, the Academia. He got a M.S. in Basic and Applied Research at the IREC (institute dependent from the Spanish National Research Council) in 2011 and a LL.B (Spanish Lic.) at the UIB in 2012. At that time, he was granted a scholarship to develop doctoral studies and got a Ph.D. in Law in 2015 and a Ph.D. in Plant Biology in 2018. At the end of 2016 he finished an EMBA at IE Business School (Madrid), and early in 2017 he was granted a postdoc scholarship at the Max-Planck-Institut für Innovation und Wettbewerb. While carrying out the research stay he was granted a scholarship waiver by the same institution to pursue the LL.M. program "Intellectual Property and Competition Law" at the MIPLC. He has also gone through the course "DL-205" from UPOV as well as

the course of "Plant Variety Protection" at Wageningen University & Research. He is the author of a book on the law of GM crops in the EU in the light of the Directive (EU) 2015/412. Currently he is working on the coordination and publication of several books on coexistence between GM maize and conventional and organic maize, as well as in a research project on the FSS in the UPOV system.

The scope of the Farm-Saved Seed under the UPOV acts of 1961 and 1978

In the UPOV Act of 1991 the farmer's privilege or Farm-Saved Seed (FSS) is expressly recognized in art 15(2). The UPOV Convention provides further guidance on the interpretation of art 15(2) in the 'Recommendation Relating to Article 15(2)', and the provision has been also addressed by the Council of UPOV in its FAQs website1 as well as in the 'Explanatory Notes on Exceptions to the Breeder's Right under the 1991 Act of the UPOV Convention'.2 However, the FSS provision is missing from the former Acts of 1961 and 1978. Some scholars have interpreted that the FSS is also accepted under the UPOV Acts of 19613 and 19784, but, beyond some scarce and vague references in the FAQs website limited to the Act of 1978, no official guidance can be found about its scope under those Acts. This presentation summarizes a study focused on the interpretation of the FSS under the UPOV Acts of 1961 and 1978, carried out in the framework of the LL.M. program "Intellectual Property and Competition Law" at the MIPLC. The current status of the research project as well as its following phases will be also sketched.

Ronald Korenstra

Ronald Korenstra (MScBA/IP) studied at the Faculty of Economics of the Rotterdam Erasmus University (EUR) and Business Administration at the Delft Interfaculty of Business Management (IBB). Later in his career he studied post-doctorate intellectual property at the University of Nijmegen. After 10 years of management positions in a leading floriculture company as partner he established a new company in trading and exporting young plants and providing consultancy services in development countries. In the early ninety's he decided to focus completely on intellectual property matters, especially plant breeders' rights. In 1998, after merging into AOMB Intellectual Property Consultants his focus was extended to trademarks and designs and he was appointed certified trademark and design attorney representing clients before the Benelux and European trademark offices BBIE/BOIP and EUIPO. As senior attorney Ronald and his staff at AOMB Intellectual Property (www.aomb.nl) provide filing services in the European Union and, through a widespread network of foreign specialists, in countries all over the world. For some larger breeding companies he is acting as world-wide counsel providing not only the aforementioned services but also IP strategy and litigation, mostly in collaboration with the international lawyers firm CMS Derks star Busmann. To exchange know-how Ronald gives lectures at the University of Wageningen, foreign business schools and several private institutions.

Rethinking the future of the Breeder's exemption, a culture clash?

Since time immemorial, plant-variety protection law has recognized a particular restriction on the rights of a holder of exclusive rights: this restriction is referred to internationally as the 'breeder's exemption'.

This very important exemption provides breeders of new varieties the possibility to use protected plant genetics to create new and improved varieties and is included in almost all plant breeders' rights legislations world-wide.

Paradoxically enough the lawyers of the same breeding companies are continuously trying to find ways to exclude the breeder's exemption from the agreements with third parties, being afraid that their varieties will be used for breeding activities. The rise of biotechnology in breeding and the international trade of plant material have in fact increase those efforts.

In a practical way the speaker will delineate these developments and will ask some relevant questions how strong the breeder's exemption is, now and in the future.

PANEL 6. PHARMACEUTICAL INNOVATIONS

Moderator

Maciej Barczewski

prof. UG, dr hab. Maciej Barczewski is Head of the Centre for Intellectual Property Law at the University of Gdańsk. He has previously taught at Chicago-Kent College of Law (US) and was a Visiting Researcher at the University of Oxford (UK). He has also served as an expert to the European Commission, the European Parliament and WIPO.

Jorge L. Contreras

Jorge L. Contreras is a Professor of Law at the University of Utah (Salt Lake City, USA). Before entering academia, Professor Contreras was a partner at the international law firm Wilmer Cutler Pickering Hale and Dorr LLP, where he practiced transactional and IP law in Boston, London and Washington DC. His research focuses, among other things, on the development of technical standards and the use, dissemination and ownership of scientific data generated. He is the author of more than 100 scholarly articles and chapters which have appeared in scientific, legal and policy journals including Science, Nature, Georgetown Law Journal, Harvard Journal of Law and Technology, Antitrust Law Journal and Telecommunications Policy. He is the editor of five books relating to technology law and technical standards, including the Cambridge Handbook of Technical Standardization Law, 2 vols. (2017, 2019 forthcoming). He has been quoted in the NY Times, Wall Street Journal, Economist, Washington Post, Korea Times, has been a guest on NPR, BBC and various televised broadcasts, and his work has been cited by the U.S. Federal Trade Commission, European Commission and courts in the U.S. and Europe. He currently serves as Co-Chair of the Interdisciplinary Division of the American Bar Association's Section of Science & Technology Law, and as a member of the National Institutes of Health (NIH) Council of Councils and the IPR Policy Committee of the American National Standards Institute (ANSI). He has previously served as Co-Chair of the National Conference of Lawyers and Scientists, and as a member of the National Academy of Sciences (NAS) Committee on IP Management in Standard-Setting Processes. He is an honors graduate of Harvard Law School (JD) and Rice University (BSEE, BA).

The patentability of genetic therapies: CAR-T and the medical treatment exclusion around the world

Since the early twentieth century, countries including the UK and Germany have considered methods of medical treatment as being beyond the scope of patentability. The European Patent Convention, which was adopted in 1973, followed this approach, stating in Article 52(4) that "methods of medical treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body" are not "susceptible of industrial application" and are thus not patentable. This precedent laid the groundwork for a similar exclusion in the TRIPS Agreement, adopted in 1994. Article 27(3)(a) of the TRIPS Agreement authorizes member states to "exclude from patentability … diagnostic, therapeutic and surgical methods for the treatment of humans and animals." These exclusions, both in the EPC and TRIPS Agreement, have led to the adoption in national law of an exclusion from patentability for medical treatments in a large number of countries.

One outlier in this regard is the United States. Traditionally, the U.S. did not exclude medical treatments from patentability. However, during the early 1990s, a debate arose in the medical community surrounding one surgeon's attempt to enforce a patent covering sutureless cataract surgery against a competing surgical clinic. The result was Section 287(c) of the U.S. Patent Act, enacted in 1997, which prohibits the enforcement of a patent covering a "medical or surgical procedure" against a "medical practitioner" and related health care entities. The 287(c) exception does not limit infringement suits against medical device or pharmaceutical manufacturers. However, medical treatment patents have come under attack from a different angle in the U.S.: whether they are eligible patent subject matter under Section 101 of the Patent Act. Since the Supreme Court's 2012 decision in Mayo v. Prometheus, many medical treatments and procedures have been ruled ineligible for patent protection as abstract ideas, natural phenomenon or mental processes.

Against this backdrop, a set of promising new technologies has emerged in recent years that utilize a patient's own cells to combat disease. These include stem cell and CAR-T (chimeric antigen receptor T-cell) therapies. Some of these therapies,

such as Novartis's Kymriah (a CAR-T based therapy), consists of a modified form of a patient's own white blood cells, uniquely tailored to that patient's tumor genetic profile. Kymriah has been submitted to and approved by the U.S. Food and Drug Administration as a new drug, yet does not contain any compound or composition of matter other than the patient's own altered blood cells. Should Kymriah then be considered a method of medical treatment? If so, it should be excluded from patentability in at least those countries in which methods of medical treatment are not patent eligible, and even in the U.S. under Sections 101 and 287(c) of the Patent Act.

This paper explores current patenting activity around CAR-T technologies and questions the validity of many of the patents currently issuing on this potentially lifesaving technology.

Marek Świerczyński

Marek Świerczyński is attorney at law at the Kieszkowska Kancelaria Rutkowska Kolasiński law firm, associate professor at the Department of Civil Law and Private International Law WPiA UKSW, author and co-author of several dozen scientific publications in the field of IPRs, IT law, pharmaceutical law and coflict of laws field. Awarded by Polish Patent Office in competition for the best postdoctoral thesis in the field of IPR. He is the permanent arbitrator at the Conciliation Court for Internet Domains in Poland and mediator at UPRP / WIPO. He is also a consultant of the Council of Europe in the field of electronic evidence. Editorial member of the Comparative Law Review, the quarterly The Law of Digital Media, „Młody Jurysta". Member of the IPR Section of the Allerhand Institute in Krakow. He was an expert in the team for the abolition of barriers in e-administration and at the ICT Committee of the Council of Ministers. He acted as a legislative expert of the Polish Employers Association in the field of medical, electronic and pharmaceutical law.

Biosimilars and patent law

In the context of patent law two basic questions concerning biological drugs arise: 1) should this kind of inventions be treated as common good (part of the public domain)? 2) What is the optimal regime of intellectual property in relation to a biosimilar medicines? Proposed changes could include modifications, such as toward creating a subtype of patent aimed at biologicals, sui generis protection of genetic components of biological drugs, strengthening the rules on business confidentiality or extension of copyright protection for the DNA sequence in the likeness of protection of computer programs. The question also arises in relation to the possibility of expanding exceptions to the scope of patent protection in relation to biotechnological inventions.

Justyna Ożegalska-Trybalska

Associate professor at the Intellectual Property Law Chair of the Jagiellonian University, lecturer of copyright, patent and trademark laws; an arbitrator at the Domain Name Court at the Polish Chamber of Informatics and Telecommunication and at the WIPO Arbitration and Mediation Centre; senior expert or coordinator in many national and international projects focusing on IP issues (IPR-Helpdesk, NetFinTex, IP-Unlink, HEIP-Link, PILA, CipaNet). In 2018/2019 a director of the Joint Master's Degree Programme in Intellectual Property and New Technologies organised by Jagiellonian University with WIPO Academy and the Polish Patent Office. As a scholarship holder she has conducted research in the field of trademark and patent law at the Columbia University School of Law in New York (2003) and the Max Planck Institute for Innovation and Competition in Munich (2017). Her recent scientific interest focuses on a comparative study on a patent infringement in Europe. Justyna Ożegalska-Trybalska is the author (co-author) of number of national and foreign publications in the field of the intellectual property law, new technologies, IP management and commercialisation, including;"Domain Name – legal issues" (2003); Domain Name Law and Practice. An International Handbook, (ed. T. Bettinger, A. Waddel, 2015), Patent Law (co-author, 2017), System of Private Law, Industrial Property Law, (co-author, ed. R. Skubisz, 14A, 2017 amd 14C, 2018).

SPC manufacturing waiver – a tool for increasing competetiveness of generic companies or a weapon detrimental for innovators

The presentation will focus on recent the EC proposal for amending the Regulation (EC) 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products by introducing new form of limitation of SPC monopoly – export manufacturing waiver. It will allow EU-based companies to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the certificate for the purpose of exporting to a non-EU market with no equivalent SPC protection. It will discuss controversies related to the proposal and tries to answer the question whether

the proposed institution would help in balancing interests between innovative and generic EU companies and increasing competitiveness of generic industry or would be detrimental for SPC holders.

Agnieszka Sztoldman

Dr Agnieszka Sztoldman joined the law faculty of University of Wrocław in 2018. Agnieszka also lectures unfair competition law at the Koźmiński University in Warsaw and is an affiliated research fellow at the Allerhand Institute in Cracow. She received her J.D. with honors and Ph.D. from the University of Warsaw. She also received her B.A. in the international trade policy. Agnieszka authored the first monograph in the CEE region on the Bolar exemption in the patent law (Wolters Kluwer 2018), awarded with the prize by the Polish Minister of Sciences and Higher Education in the competition for the best doctoral dissertation organized by the Polish Patent Office (2017). Her teaching and research interests include domestic and international intellectual property law including litigation aspects, as well as civil law and unfair competition. She is a practising attorney-at-law and co-heads one of the IP teams in the renowned law firm in Warsaw.

Reconsidering the Bolar exemption: is the legislative framework fit for purpose?

We live in a business world that increasingly worships the great god innovation, lyrically hailing it not just as a desired, but as a necessary, condition of a company's survival and growth. Under the essential idea the Bolar exemption facilitates generic producers to introduce generic products in the market immediately after the patent has lapsed and when the invention falls into the public domain. But is it really the case that the Bolar rule serves only the generic drugs industry or rather generally facilitates innovation? Is it a hindrance or can it facilitate innovation in local pharmaceutical industries?

Offered locally in the EU, this regulatory review differs and there is only slim guidance from the courts. Uncertainty as to which acts fall within this regulatory review creates infringement risks on the European pharmaceutical market. The fragmented legislation results in a cost burden to some stakeholders. The scale of these costs varies depending on the patent landscape that surrounds the drug(s) used in a trial.

For example – with respect to developing combination products, local differences due to European law implementation may cause significant costs associated with clearing-the-path to carry out clinical trials, specifically listing opposition and revocation proceedings as well as freedom-to-operate studies. When combined with low success rates in phase II and III clinical trials, large sums of money are spent on products which never reach market.

In my paper I analyse the following issues concerning this regulatory review:

- *how far does the "functional" link between the activities and legislative purposes of the Bolar exemption reach?*
- *what activities are covered: collecting data for marketing and/or use for public health procurement?*
- *whether it applies to clinical trials on biosimilar or innovative drugs for the purpose of obtaining a marketing authorisation?*
- *whether the current wordings of the local legislations does not provide enough protection to avoid the possibility that some clinical trials with innovative or biosimilar drugs may lead to the threat of legal action?*
- *what is the relation between the "local" Bolar exemption and the "unitary" regulatory review?*
- *should the regulatory review be territorially decomposed within the EU?*

My paper hence analyses the model-shape of the Bolar exemption enabling it to settle the competitive interests of innovative and follow-up life sciences products.

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