

Patentability issues in the fields of pharmacy and biotechnology

Programme

Discussion platform
Event OT05-2018
9 May 2018

Organised in co-operation with:

European Patent Academy
European Patent Office (EPO)
Bob-van-Benthem-Platz 1
80469 Munich
Germany

Roundtable: Polish industry, academia and patent attorneys, PPO and EPO

Venue: Patent Office of the Republic of Poland,
al. Niepodległości 188/192, 00-950 Warsaw, Poland

Moderated by *Małgorzata Kozłowska*, patent examiner, PPO

08.45

Registration

09.00

Welcome

Alicja Adamczak, President of the PPO
Niels Stevnsborg, Senior Content Expert, European Patent Academy,
EPO

09.15

Patenting in pharmacy and biotechnology at the EPO
and the PPO: facts, figures and trends

Jörg Konter and *Giovanni Macchia*, patent examiners, EPO
Joanna Chylińska, patent examiner, PPO

09.40

Search and examination practice in pharmacy and biotechnology
at the EPO and at the PPO – résumé of the procedures

Search practice at the PPO

- ❖ Challenges concerning drafting search reports and written opinions in the fields of pharmacy and biotechnology (unity, novelty, inventive step, disclosure)

Małgorzata Kozłowska, patent examiner, PPO

Examination practice at the EPO – résumé of the procedures
(main steps)

Giovanni Macchia, patent examiner, EPO

10.15

Coffee break

10.45

Inventions in pharmacy and biotechnology: how to meet patentability requirements; main issues related to patentability

Giovanni Macchia, patent examiner, EPO

Disclosure of biological material according to the Polish patent law

- ❖ Deposits of biological material – national deposits and requirements under the Budapest Treaty
- ❖ Genes disclosure (and a short review of the law and practice at the PPO and in other countries)

Ewa Waszkowska, patent examiner, PPO

11.30

Patenting in pharmacy and biotechnology at the EPO: case law

- ❖ Selection inventions
- ❖ Decisions of the Boards of Appeal of the EPO
- ❖ Recent G decisions (disclaimers, dosage regiment), recent landmark decisions in pharma and biotech

Jörg Konter, patent examiner, EPO

12.15

Experience of a Polish company in pharmacy and biotechnology

Patentability of inventions relating to methods of treatment – the way of protecting a medical use in the context of different patent systems

- ❖ Drug development and the ways of providing exclusivity
- ❖ Different ways of protecting a medical use
- ❖ Why we need second medical use claims – drug repurposing and personalized medicine
- ❖ Practice in selected jurisdictions
- ❖ Cases from our practice and tips for Polish applicants

Anna Grzelak, patent attorney, WTS

Problems with known sequences in fusion proteins

- ❖ Augmentation of TRAIL activity – discovery of a new mechanism
- ❖ Many working embodiments – what are the common technical features and how to form a group?
- ❖ Definition in terms of function – is there any other way for structurally remote proteins providing the same technical effect?
- ❖ Is the prior art really novelty destroying? – dig up EPO arguments or your own grave
- ❖ Definition in terms of function vs prior art teaching and clarity
- ❖ 2 + 2 must make 5 for inventive step – simple sum of effects is not enough

Katarzyna Matusiewicz, patent attorney, Adamed

Significance of IP rights in pharma sector

- ❖ The role of patents
- ❖ Importance of extension of the life of pharmaceutical patents by Supplementary Protection Certificates (SPCs)
- ❖ Expected years of protection in Poland after launch in the EU

Jolanta Chlebicka-Dominiak, Legal Counsel

13.15

Plenary discussion on patenting activities in the fields of pharmacy and biotechnology

Topics to be discussed include but are not limited to:

- ❖ Patenting practices and field-specific hurdles as perceived by the audience
- ❖ Communication between examiners and applicants

Chair: *Rafał Witek*, patent attorney, WTS

13.45

Closing remarks

Piotr Czapllicki, Director, Patent Examination Department, PPO
Niels Stevnsborg, Senior Content Expert, European Patent Academy, EPO

14.00

Lunch

15.00

End of the public event

Speakers

Jörg Konter

Patent Examiner

Healthcare, Biotechnology and Chemistry

European Patent Office, The Hague

Jörg Konter is a Pharmacist and holds a PhD in Medicinal Chemistry. He worked as a research scientist in the field of Proteomics for the Bayer AG before joining the EPO in 2008 as a patent examiner in Galenics.

Additionally, as part of the Continuous Knowledge Transfer team, he gives in-house training courses for fellow examiners.

Giovanni Macchia

Patent Examiner

Healthcare, Biotechnology and Chemistry

European Patent Office, The Hague

Giovanni Macchia is a Molecular Biologist. He worked as a research scientist and as head of molecular biology laboratory in different research centres of pharmaceutical companies before joining the EPO as a patent examiner in Biotech.

At the EPO he is involved in search and examination of patent applications, classification, as well as in opposition procedures, as first member and chairman.

He passed the European qualifying examination in 2015.

Małgorzata Kozłowska

Patent Examiner, Head of Biotechnology and Pharmacy Division

PPO

Ms Kozłowska has a PhD in chemistry from the University of Warsaw. She joined the Polish Patent Office in 2007 and works as a patent examiner in the field of biotechnology. Since 2013 she has been holding the position of Head of Biotechnology and Pharmacy Division. In 2017 she completed post-graduate studies in Industrial Property Law at the Faculty of Law and Administration of the University of Warsaw.

Joanna Chylińska

Patent Examiner, Biotechnology and Pharmacy Division

PPO

Ms Joanna Chylińska holds an MSc degree in chemistry from the Warsaw University of Technology. She first worked at the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products where she focused on registration of biocidal products. She joined the Polish Patent Office in 2006 and works as a patent examiner mainly in the field of biocides. Ms Chylińska has broad experience in classification, search and examination of patent applications.

Ewa Waszkowska

Patent Examiner, Biotechnology and Pharmacy Division PPO

Ewa Waszkowska is a Biologist, holds a PhD in Biochemistry. She worked as a research scientist in the field of photobiology in the Institute of Biochemistry and Biophysics of the Polish Academy of Sciences. She joined the PPO in 2000 and worked as a patent examiner in core areas of biotechnology.

Anna Grzelak

Polish and European Patent Attorney Partner of WTS Patent Attorneys Witek, Śnieżko and Partners, Warsaw, Poland

Ms Grzelak holds a PhD in biology with a specialisation in genetics from the University of Warsaw, and a master's degree with a specialisation in microbiology from the University of Warsaw.

She first worked as a scientist and after obtaining her PhD, as a biotechnology specialist in IP. Since 2008 she has been working as a Polish Patent Attorney and since she passed the European Qualifying Examination in 2014 also as European Patent Attorney.

Ms Grzelak obtained a post-graduate diploma in Industrial Property Law at the Faculty of Law and Administration of the University of Warsaw. She has participated in postgraduate studies on European Patent Law at CEIPI, the University of Strasbourg, France. In 2015 she was at Praktika Intern in the European Patent Office in The Hague.

As a Polish and European Patent Attorney and Partner at WTS Patent Attorneys she services leading global biotechnological, pharmaceutical, veterinary and chemical companies as well as Polish scientific institutions, universities and SMEs in matters relating to the protection of inventions. Ms Grzelak is a member of the Polish Chamber of Patent Attorneys, the Institute of European Patent Attorneys and AIPPI. For a few years she was IP advisor for the University of Warsaw.

Rafał Witek

Polish and European Patent Attorney Partner and co-founder of WTS Patent Attorneys Witek, Śnieżko and Partners, Warsaw, Poland

Mr Witek obtained his degree in biotechnology from the Wrocław University of Technology. He participated in postgraduate studies on industrial property protection at the Humboldt University in Berlin. He was granted a scholarship for research at the Max-Planck Institute of Industrial Property Protection and Tax Law in Munich. He specialises in the protection and commercialisation of inventions in the fields of biotechnology and pharmacy.

Mr Witek is a member of the Polish Chamber of Patent Attorneys and the Institute of European Patent Attorneys, an associate member of the EPI Committee on Biotechnological Inventions and a former President of the LES Poland. He is also a member of AIPPI, FICPI and EPLIT. He has conducted many court proceedings before the Polish Patent Office and civil courts, in cases concerning patent invalidation as well as in matters concerning their infringement.

Katarzyna Matusiewicz

Patent attorney at Adamed group

Katarzyna Matusiewicz is a biotechnologist. She worked in the field of bacterial pathogenesis at Medical University of Wrocław and as a research scientist screening small molecules activity for Adamed. Since 2008 she is involved in analysis of patentability and FTO of pharmaceuticals.

She passed the European qualifying examination in 2017.

Jolanta Chlebicka-Dominiak

Legal Counsel

Pharma, Healthcare, Biotechnology

Novartis, Poland

Jolanta Chlebicka-Dominiak has practised in the field of EU and PL pharmaceutical and competition law for over 20 years. She has particular expertise in the pharmaceutical and life sciences sector, advising on a number of investigations and litigation actions in the industry. She joined Novartis from Johnson&Johnson where she was a Senior Counsel responsible for all EMEA Lifescan competition law matters and competition law compliance.

