

**Patent Workshop**  
**“Patentability of biological materials, isolated or derived from living organisms”**

**Monday, November 19th, 2018,**  
**Peacock Ballroom 1, Pullman Hotel**  
**13:15 - 17:15 hours**

a. Speakers

- i. Mr. Hari Subramaniam, Subramaniam and Associates (India);

*Protection of Biological Materials in India – Patent Truths and Untruths*

- ii. Dr. Yuh-Gang Yoon, Yuhgang Patent & Law Firm (South Korea); and

*Patentability of Biological Materials: Differences in patentability of an isolated gene in the U.S.A, Australia and Korea; and the strategies to protect the isolated gene.*

- iii. Mr. David Postolski, Gearhart Law LLC (USA)

*US Patentability of Biological Materials, Isolated or Derived from Living Organisms*

- b. Moderator – Mr. Peter Claassen, Benelux Lawyers (Netherlands).

## Summary of Presentation and Speakers' Profile



**Mr. Hari Subramaniam**

Speaker

### **“Protection of Biological Materials in India – Patent Truths and Untruths”**

India is one of the few jurisdictions where the statute has a negative list which excludes certain classes of inventions from patentability even if they are novel and non-obvious. Thus, many inventions relating to biological material are rejected not on the basis of judicial interpretations but based on facts and statute. The Indian law specifically precludes from patentability plants and animals (except microorganisms) in whole or parts thereof, seeds, varieties, and species. It also prohibits naturally occurring substances and essentially biological processes. There have been instances where cell lines, stem cells, nucleotide sequences, genes and monoclonal antibodies have been rejected as being naturally occurring while in other cases, they have been allowed. In such cases, the question of patentability was based on whether there was any human intervention, at what stage the human intervention took place and whether such human intervention was novel and inventive. This presentation will bring the audience up to date with the peculiarities and impediments of the Indian statutes, recent decisions of the Indian Patent Office and Intellectual Property Appellate Board and ways and means by which the hurdles of the Indian law may be negotiated.

### **Speaker's Profile:**

*Hari Subramaniam* is an attorney-at-law and a Registered Patent Agent with a background in Physics, Chemistry, medicine, biological and life sciences. He has been in practice for the last 38 years, specialising in all aspects of intellectual property law matters. In the course of the career, he has filed, prosecuted, defended, opposed and/or enforced directly or in supervisory capacity over 40,000 Patent matters in India and abroad relating to all areas of technology. He has had several “firsts” to his credit in all areas of technology and has been widely acclaimed for his skills in providing solutions to most complex issues during prosecution and oppositions. He was the first person to initiate black box (mail box) applications in India under the GATT/TRIPS Agreement for pharmaceutical products.

He has been called upon several times as an expert witness before the Joint Parliamentary Committee for the amendment of patent laws in India. He is regularly called upon as a faculty or speaker in several seminars, conferences and Patents Awareness workshops conducted by the Government of India, WIPO and various International Organisations, American Bar Association, INTA, AIPPI, APAA, IPO, Patent Offices and universities across the world. He is also often called upon to train Patent Examiners and judicial Officers. He speaks in at least four International Fora every year across the Globe in diverse IP related issues. He has also authored several papers relating to key issues on various aspects of Intellectual Property laws.

He has been in the Pharma and Biotech Committee of AIPPI for several years and is a regular speaker in Pharma workshops of AIPPI. He is the longest serving APAA Council Member from India and has spearheaded the Patent Committee of Indian Group in the APAA Standing Committee on four different occasions. He has served as International Vice President of APAA for several years, and is the President of APAA Indian Chapter. He was a co-Chair of the organising Committee of APAA 2005 and 2018.



**Dr. Yuh-Gang Yoon**  
Speaker

**“Patentability of Biological Materials: Differences in patentability of an isolated gene in the U.S.A, Australia and Korea; and the strategies to protect the isolated gene”**

As to an isolated gene, U.S. supreme court ruled that it is not patentable because there is no “significantly more” from the natural product even if it is purified from natural product. Thus an isolated gene is not patentable because it could not meet the requirement of “...new ...composition of matter according to the article 101 of U.S patent law. In Australian High Court also denied the patentability of the isolated gene because the essential element of the invention of BRCA gene is a genetic information and the genetic information is not distinguishable from the information stored in human body. Australian High Court even more denied the patentability of cDNA. On the contrary to U.S.A and Australia, most of counties including Republic of Korea allow patents to the isolated gene. The scope of protection to the isolated gene differs in U.S.A., Australia and Korea. One of the interesting things is that human therapeutic methods and human diagnostic method are patentable in U.S.A and Australia which is different from the international practices which do not allow a patent to human diagnostic or therapeutic invention. Such different patent protection system to an isolated gene makes lots of confusions. Thus, international consensus to patentability of isolated gene are required.

**Speaker’s Profile:**

*Yuh-Gang Yoon* is the founder of Yuhgang Patent & Law Firm, and the patent attorney in-charge of the firm’s biological and chemical-related cases. Dr. Yoon is a specialist in the field microbiology, and has a strong technical background in chemistry, computational biology, bioinformatics, bioengineering, proteonomics, metabolic engineering and phylogeny.



**Mr. David Postolski**  
Speaker

### **“US Patentability of Biological Materials, Isolated or Derived from Living Organisms”**

This presentation will bring practitioners up to date on recent U.S. case law regarding the patentability of biological materials, whether isolated or derived from living organisms including a discussion on blockbuster Supreme Court decisions in *Mayo Collaborative Services v. Prometheus* and *Association for Molecular Pathology v. Myriad Genetics*. These landmark decisions are having lasting effects on the life sciences industry. The presentation will explore what effects these decisions have had on the industry and on United States Patent examination guidelines for biologic materials, nature based products and deposit rules for biological materials. The presentation will also discuss recent patent events surrounding CRISPR 9.

#### **Speaker’s Profile:**

*David Postolski*, a partner at Gearhart Law, is a registered patent attorney and Intellectual Property attorney. With over 17 years’ experience, David specializes in assisting inventors, creators, artists, start-ups, entrepreneurs, early stage companies and emerging companies with their U.S and International intellectual property strategy, protection, enforcement and monetization. David is a frequent speaker and author on intellectual property issues surrounding emerging technologies (cannabis, crypto currency, 3d printing, gig economy), raising capital, business formation, licensing, and reward and equity based crowd funding. David is also a Professor at Parsons School of Design where he teaches master level students about IP, ethics and other regulatory considerations in starting business ventures and products around design.

David’s life sciences industry experience includes counseling, drafting and prosecuting U.S. and Foreign patent applications in the fields of chemistry, biochemistry, physics and chemical engineering. He has prosecuted applications with subject matter including but not limited to thermodynamics, thermometry, paramagnetism, hyperpolarization, carbon dioxide emissions and effects, medical devices, a variety of healthcare products and pharmaceuticals. His experience also extends to the corresponding branding, trademark, business and corporate side of intellectual property, including drafting and negotiating licenses, product development, manufacturing and launch, FDA processes, ANDA procedures and consumer product safety commission processes.



**Mr. Peter Claassen**  
Moderator

*Peter Claassen* studied law at Nijmegen University where he obtained his Master degree. In addition Peter obtained an LLM degree at Miami Law school. In 1984 he worked for a year at Arnall Golden & Gregory, Atlanta, U.S.A. In 1985 Peter started working at AKD where he became a partner in 1992.

Peter has expertise in a wide range of the legal arena. Peter has paid a great contribution to the expansion of AKD's IP practice and the Retail & Consumer Products branch group. His main expertise is in the classic IP areas such as patents, trademarks, designs and copyright. Peter is regarded as an experienced litigator. A large number of the cases in which he has conducted litigation have been published in specialist literature. In addition Peter has wide experience with the legal aspects of brand development, parallel trading and drafting of IP agreements such as licences, transfers and distribution agreements.

Peter's clients include both nationally and internationally renowned companies in the following branches: chain stores, electronics, food & beverages, household & personal care, fashion and leisure wear, design and information and communication technology.

Peter chairs the IP&T practice group and is a member of leading organisations such as INTA and Marques. He regularly teaches on the subject of trademark and patent law and gives lectures at seminars both at home and abroad.