한 국 바 이 오 협 회

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문서번호 한바협 제16-078호
일 자 2016. 03. 02
수 신 회원사 및 바이오기업, 기관
참 조
제 목 의약품 미국 특허소송 및 허가등록 전략 세미나 개최 안내

1. 귀 사의 무궁한 발전을 기원합니다.

2. 우리 협회는 국내 제약·바이오기업이 의약품의 미국시장 진출을 준비함에 있어 핵심 장애요소인 ANDA(Abbreviated New Drug Application:약식 신약 신청서)소송과 관련해 소송 전 준비단계에서부터 소송의 종결에 대한 전문적 지식 공유하고, 국내 기업의 미국 시장 진출을 지원하고자 아래와 같이 세미나를 개최하오니 많은 참석 바랍니다.

- 아 래 -

가. 행사개요
- ○ 행 사 명 : Global Drug Development Seminar
  - Strategies for US ANDA litigation and Regulatory affairs
- ○ 일 시 : 2016. 3. 15(화) 13:30~18:00
- ○ 장 소 : 벨레상스호텔(구. 르네상스 호텔) 3층 다이아몬드 hall
- ○ 주 최 : 한국바이오협회, 충북테크노파크, 한국특허정보원 특허정보진흥센터
- ○ 후 원 : Sughrue Mion, PLLC
- ○ 프로그램 : 붙임참조
- ○ 참가대상 : 의약품의 미국진출에 관심 있는 회원사 및 비회원사

나. 참가신청
- ○ 신청기한 : 2016년 3월 14일(월) 10:00까지 온라인 신청
- ○ 참가신청 : http://koreabio.org/event/event_form.php?event_no=75
- ○ 문 의 : 한국바이오협회 최유미 과장(youme@koreabio.org, T. 031-628-0042)

※ 붙임 : 1. 프로그램 1부. -끝-.

한 국 바 이 오 협 회

회장 서 정 선 직인 생략

Global Drug Development Seminar
의약품 미국 특허소송 및 허가등록 전략
Strategies for US ANDA litigation and Regulatory affairs

☐ 행사개요

- ◦ 명 칭 : Global Drug Development Seminar
  - Strategies for US ANDA litigation and Regulatory affairs
- ◦ 일 시 : 2016. 3. 15(화) 13:30~
- ◦ 장 소 : 벨레상스 호텔(구. 르네상스 호텔) 3층 Diamond hall
- ◦ 주 최 : 한국바이오협회, 충북TP, 한국특허정보원 특허정보진흥센터
- ◦ 후 원 : Sughrue Mion, PLLC
- ◦ 참석자 : 바이오·제약 및 관련 기업 특허 및 허가등록 담당자 등 100여명

☐ 개최목적

- ◦ 국내 제약회사들이 제네릭 의약품으로 미국시장 진출을 준비함에 있어 핵심 장애요소인 ANDA(Abbreviated New Drug Application:약식 신약 신청서)전략을 주제로 함
- ◦ ANDA 소송과 관련해 다양한 제약회사들을 대리하며 소송 전 준비단계에서부터 소송의 종결까지 광범위한 현장 경험을 쌓은 미국 5대 로펌(Sughrue Mion, PLLC)소속 전문가들이 주제발표

□ **프로그램(안)**

시간	행사 내용	발표자
13:00-13:30	Registration	
13:30-13:40	Opening Remarks	
13:40-14:10	Obviousness of compound patent and post-filing evidence showing actual differences between a patented invention and the prior art in *Bristol-Myers Squibb v. Teva* 화합물 특허의 자명성 판단에 있어서, 특허된 발명과 선행기술의 차이점을 보여주는 출원일 이후의 증거자료의 사용 (Bristol-Myers Squibb v. Teva)	Sughrue Mion Chid Iyer
14:10-14:50	Hatch-Waxman cases you should know for drug developments and ANDA filing 의약품 개발과 ANDA 신청을 함에 있어 반드시 알고 있어야 할 Hatch-Waxman 소송 사례	Sughrue Mion Mike Dzwonczyk
14:50-15:20	Next Big Drug: Biosimilar Litigation Updates, including related IPR 현재 진행 중인 바이오시밀러 소송 및 이들 소송과 관련된 USPTO IPR 소송 업데이트	Sughrue Mion Sunhee Lee
15:20-15:30	Break	
15:30-16:10	Exploring use of USPTO trial proceedings (IPR) in Hatch-Waxman litigation Hatch-Waxman 소송과 관련하여 USPTO IPR을 효과적으로 이용하기 위한 전략 및 현황	Sughrue Mion Mark Boland
16:10-17:00	Networking	

※ 상기 일정 및 강연자는 사정에 따라 변경될 수 있음

□ 강연자

Sughrue Mion, PLLC
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■ Profile

Mr. Boland has successfully represented a variety of companies in the U.S., Asia and Europe as lead counsel in numerous patent litigations before federal district courts and the U.S. International Trade Commission. His experience includes jury trials, bench trials and appeals before the Federal Circuit. He has also successfully represented clients in patent interferences before the USPTO and district court § 146 interference appeals.

Mr. Boland also regularly engages in patent infringement and validity opinion practice and counseling, freedom-to-operate, due diligence and product clearance work, licensing and contract matters including joint ventures and co-development situations, patent application preparation and prosecution, and counseling clients in devising global intellectual property strategies.

Mr. Boland advises companies involved in a variety of technologies, particularly pharmaceutical, chemical and biologically-oriented technology, as well as the mechanical arts. Mr. Boland is a member of the firm's Management Committee.

Sughrue Mion, PLLC
Michael R. Dzwonczyk
Partner | Washington
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■ Profile

For 25 years, Mr. Dzwonczyk has successfully represented multinational companies as lead counsel in trials and appeals of patent cases in District Courts and at the Federal Circuit, as well as Section 337 cases at the International Trade Commission. His experience has encompassed technical areas that include recombinantly produced hormones, pharmaceuticals, protein synthesis and expression products, fibers, films, polymers, plastics and medical devices. Mr. Dzwonczyk also counsels clients on intellectual property issues, including validity and infringement of intellectual property rights, licensing and contract matters and Hatch-Waxman issues.

He has lectured on numerous topics including strategies for opinion drafting, pharmaceutical litigation strategies, AIA procedures, compulsory licensing, and Patent Law Reform. He is the former Chair of FCBA's amicus committee, a former member of its Board of Directors, as well as a former Chair of the AIPLA Chemical Practice Committee. Prior to working as a patent attorney, Mr. Dzwonczyk worked at FMC Corporation agricultural chemicals research facility on the synthesis, isolation and characterization of novel plant growth regulators, herbicides and insecticides.

Mr. Dzwonczyk is an adjunct professor of law at George Washington University's National Law Center, where he co-teaches International and Comparative Patent Law. He has been quoted by The Washington Post, The Legal Times, The Corporate Legal Times, Bloomberg News Service, The IP Law Bulletin, and others.

He was named in the 2014 IAM Patent 1000 list of The World's Leading Patent Practitioners, and described as a leading expert in the 2014 Financier Worldwide Corporate Advisor Handbook for Intellectual Property.

Mr. Dzwonczyk is a member of the Firm's Management Committee.

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■ Profile

Mr. Iyer's practice includes patent litigation and prosecution in complex technical areas in the electrical and computer arts. His representative cases include multi-patent litigation in the field of semiconductor memories and AI software. Mr. Subramanian has also been in involved in patent infringement cases pertaining to electrical motor control systems and chemical software.
Mr. Iyer has prepared and prosecuted over fifty applications for a leading computers and communications research laboratory. In addition, he prepared and prosecuted a substantial number of applications in the areas of computer network hardware and software; VLSI design, testing and performance; software and algorithms for various applications; semiconductor processing; and bioinformatics. Mr. Iyer also engages in general client counseling including validity and infringement opinions in the above areas.

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■ Profile

Ms. Lee is a member of the firms Biotechnology/Pharmaceutical Group. She has extensive experience in prosecuting patent applications and writing opinions regarding patentability, infringement and freedom-to-operate. Ms. Lee's work focuses on biotechnology area including nucleic acid and polypeptide sequences, antibodies, pharmaceuticals, and regenerative drug areas. Her work also covers drug delivery systems. She was a member of the firm's litigation team for the recent AZ v. Hanmi in the District Court of New Jersey, which was the Korean drug companies' first US Hatch-Waxman litigation.
She is named in the 2015 Rising Stars within the Washington DC metropolitan area by the Washington DC Super Lawyers Magazine. She speaks fluent Korean and is a registered Korean Patent Attorney.
Ms. Lee serves as a co-chair of the Asia Pacific Committee of the AIPLA AIPPI US division, a co-chair of the International Cooperation Committee of the Korea Patent Attorney Association (KPAA), and a Korea Innovation Center (KIC) Washington DC leadership mentor. She also served as a president of the KAIPBA.