

# BIOLOGICS AND BIOSIMILARS & BIOPHARMA & BIOTHERAPEUTICS

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### **“Why so serious?”– The increasing impact of post grant challenges to biologics and biosimilars in the US**

Biologics and biosimilar products are the fastest growing pharmaceutical products in the US, being 3 of the top 5 best selling pharmaceutical products in the US in 2018. As such, it has become even more important to companies in both the biologics and biosimilars space to acquire and protect related intellectual property, as well as conduct a thorough analysis concerning potential infringement and validity issues of competitor intellectual property. The supreme court has now upheld the constitutionality of inter partes review and post grant review as viable avenues for challenging patentability and recent developments with the federal circuit have potentially increased the likelihood of challenges, particularly with respect to the very important area of biologics. We will take a look at the IPR and PGR processes, discuss strategies for filing and responding to these petitions, consider recent case law and its impacts on these processes and provides insight as to what steps to take to prepare for a potential future challenge.

#### **Biography**

Ha Kung Wong practices general intellectual property law with an emphasis on complex patent and trade secret litigation in pharmaceuticals, biologics and chemistry. Cases he has litigated include those related to proton pump inhibitors, anti-epileptic drugs and other pharmaceuticals. He has also extensive experience with inter partes review (IPR), intellectual property counseling, pre-suit investigations, licensing and due diligence. He is the recipient of the 2017 ILO Client Choice Individual Award For Intellectual Property in New York. He is currently the chair of the recruiting committee, serves as faculty for NITA (the National Institute of Trial Advocacy) and Lawline and has been named a "Furthered 40" by Lawline for his contributions. He is also an advisory board member for the center for biosimilars. He was named to The National Law Journal's 2017 inaugural list of Elite Boutique Trailblazers. He holds a B.S. in chemistry and biochemistry of the University of Illinois Urbana-Champaign and J.D. for the University of Notre Dame Law School.

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