Michael Johnson
Partner
Willkie Farr & Gallagher LLP

Michael Johnson is a partner in the Intellectual Property Department at Willkie. Michael's practice focuses on litigation concerning patents, copyrights, and trade secrets. His litigation experience encompasses an array of technologies, including pharmaceuticals, biotechnology, medical devices, industrial chemicals, and consumer products, with particular focus on pharmaceuticals and biotechnology.

In the pharmaceutical field, Michael has played a significant role in litigations and PTAB proceedings involving biologic and small-molecule drug products. In addition, Michael has prevailed in several appeals following trials and preliminary injunction decisions. Michael’s practice also includes client counseling on patent infringement, validity, and enforceability, as well as IP issues associated with transactional work, including licensing and mergers.

Anthony Lo Cicero
Partner
Amster Rothstein & Ebenstein LLP

An engineer by training, Tony has represented companies in patent and trademark litigation involving product areas as diverse as e-commerce platforms, angular rate sensors, refrigeration chemistry, camcorders and textiles. He conducts due diligence of IP portfolios and provides strategic patent counseling to companies in a wide range of industries from recorded and published music to consumer electronics.

Very sophisticated technology competes with style and price as key aspects of the customer experience in the fashion industry. Tony represents some of the most prominent brick-and-mortar and on-line retailers in the country in patent disputes relating to the enterprise's e-commerce, mobile and point of sale systems. Tony also evaluates contractual terms with vendors and suppliers to mitigate liability and works with retailers to identify and obtain protection for their own innovations.

Restaurants, financial institutions, insurance companies, health care institutions, consumer product manufacturers and other businesses like-wise rely on technology to bind customers, improve the customer experience, differentiate themselves and stimulate demand. Tony advises clients on freedom to operate issues, prosecutes patents and defends them in litigation.

Many of the most prestigious apparel manufacturers and retailers in the world, along with financial services, food products, computer, consumer electronics, home products, and toy companies also turn to Tony for trademark protection. He advances brand development and enforcement strategies ranging from anti-counterfeiting and trademark infringement protection to trade dress and Internet domain matters. For example, he overcame significant legal obstacles to protecting a name and symbol for what is now one of the best-known prestige brands in the country. On many occasions, he has been called upon to enforce trademark rights for entities that do not have the advantage of a federal trademark registration.

Tony was actively involved in shaping the Trademark Anti-counterfeiting Act of 1984, and served on the board of the International Anti-counterfeiting Coalition during seminal efforts to strengthen the protection of federal and state laws. Similarly, he represents companies based in Europe, Asia and Latin America in protecting their trademark rights in the United States.

Tony is a past President of the New York Intellectual Property Law Association and is currently co-chair of its Legislative Action Committee.

Nineteen Hundred and Twenty-two
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Legislative Update
NYIPLA Legislative Action Committee
Anthony F. Lo Cicero, Jeffrey M. Butler, Co-Chairs

Panelist: Anthony F. Lo Cicero

Moderator: Michael Johnson

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Introduction

- As intellectual property has grown in importance, public interest in what was once an arcane field has grown as well
- Congress has tapped into this public interest and views intellectual property as an issue of national importance
- Accordingly, Congress is now considering legislation in all fields of intellectual property
- This presentation will try to hit the highlights

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Patent Eligibility

- Since the Supreme Court's *Alice* and *Mayo* decisions, the standards for patent eligibility may be said to be in flux
- Scholars, commentators and some judges have opined that only legislative changes to Section 101 will be able to solve the problem. The NYIPLA has endorsed this approach
- A subcommittee of the Senate Judiciary Committee has invited stakeholders to consider legislative approaches

Patent Eligibility

- Potential approaches include:
  - A definition of "useful" that includes utility in any field of technology
  - Elimination of the word "new" from Section 101
  - Requirement that patent eligibility be determined by considering the invention as a whole
  - Provision that Section 101 should be the sole factor in determining patent eligibility – not "judicial exceptions"
  - Requirement that patent eligibility be determined without regard to sections 102, 103 or 112
  - Modification to Section 112 to eliminate concerns about overly broad computer-related inventions

Pharma Proposals - In General

- During this political season, several proposals have been made with respect to pharmaceutical products. Many of these seek to lower drug prices.
- The following discussion will deal only with those proposals which directly relate to patent issues

Pharma Proposals – Product Hopping/Patent Thicketing

- S. 1416 (As introduced) deemed patent "thicketing" and "product hopping" as presumptively anticompetitive
- "Patent thicketing" in the originally introduced bill meant actions by one patentee, to limit competition, by which it (i) obtains patents in the same patent family or patent portfolio (ii) that claim the drug, a form of the drug, a method of using it, or a method of making it, and (iii) whose effective filing dates post-date the application filing date of the new drug application (NDA) or biologics license application (BLA).

Pharma Proposals – Product Hopping/Patent Thicketing

- As an alternative to (i-iii), "patent thicketing" also applies if *"the underlying composition of matter patent is found invalid* [emphasis added] and the patentee obtains patents in the same patent family or patent portfolio that claim the drug or biological product or a use of the drug or biological product, a form of the drug or biological product, a method of use of the drug or biological product, or a method of manufacture of the drug or biological product."

Pharma Proposals – Product Hopping/Patent Thicketing

- In response to pushback from certain stakeholders … in lieu of the "patent thicketing" prohibition, in the current pending version of S. 1416 (and related bill H.R. 3991) [current as of ca. 28th October] — "thicketing" has been replaced by a modification to the so-called "patent dance" called for in the BPCIA (42 U.S.C. § 262); namely:
- 35 U.S.C. § 271(e) would be amended to limit the number of patents that a "reference product sponsor" (RPS) could assert against a "351(k)" biosimilar applicant, if the RPS brings an infringement action under § 271(e) against the 351(k) applicant
- Subject to certain restrictions, the RPS could assert not more than 20 patents, and not more than 10 of which issued after BLA application date
- The types of patents subject to the above numeric limitation are patents that:
  - *Claim the biological product that is the subject of the 351(k) application or a method or product used in the manufacture of such product; and*
  - *Are included on the 351(l) "patent dance" lists; and*
  - *(I) have an actual filing date more than 4 years after the date on which the reference product is approved or (II) include a claim to a method in a manufacturing process that is not used by the reference product sponsor.*

Pharma Proposals – Product Hopping/Patent Thicketing

- "Product hopping" may be considered the situation in which a pharmaceutical developer creates a reformulation of a drug and uses the market approval process regulated by the FDA to prevent generic substitutions tied to the old formulation from entering the market.
- Product hopping would be considered an anticompetitive activity unless pharmaceutical patent owners demonstrate that the anticompetitive nature of the action does not outweigh the pro-competitive effects of the action, or otherwise achieves some clinically meaningful improvement in safety or therapeutic benefits.

TERM Act

- TERM (Terminating the Extension of Rights Misappropriated Act of 2019 (H.R. 3199))
- Proposed legislation would create a presumption in any Hatch-Waxman or BPCIA proceeding in which the validity of an asserted patent is challenged
- The presumption is that the term of any subsequently obtained patent covering a drug or biologic product will be disclaimed over the term of the "first patent" (e.g., presumably the compound or composition-of-matter patent first listed in the Orange Book)
- Presumption is rebuttable if the patentee can prove by a preponderance of the evidence that the second patents are "patentably distinct" from the "first patent."

TERM Act

- Potential Concerns:
  - Bill does not clearly define the term "first patent"
  - Bill is not clear on how a patentee can prove any subsequent patent to be "patentably distinct" from the first patent and thus fall into one of the bill's exceptions.
  - Bill could substantially complicate patent litigation, where, in one proceeding, two different presumption standards could apply
  - The presumed disclaimer of patent term could lead to challenges that provisions in the proposed legislation violate the Fifth Amendment's Takings Clause

Copyright Proposal – CASE Act

- Small-Claims Enforcement (CASE) Act of 2019 (H.R. 2426).
  - Would provide for a small claims enforcement proceeding within the Copyright Office
  - Damages would be limited to US$15,000 for each infringed work, and $30,000 total per claim
  - Respondents would be able to opt out (based on the Seventh Amendment right to a jury trial)

Patent Proposal – STRONGER Act

- Support Technology & Research for Our Nation's Growth and Economic Resilience
- Inter Partes Reviews and Post Grant Reviews
  - Harmonize standard for claim construction
  - Harmonize burden of proof for finding invalidity
  - Specify standing requirement for IPR/PGR
  - Eliminate repetitive PTAB proceedings
  - Review institution decisions
  - Eliminate redundancy with district courts
  - Gives priority to district court decisions
  - Establishes presumption of irreparable harm upon a finding of infringement

Trademark Proposals –Pre Registration

- **Provision for third party submission of evidence during examination (codification of "Letter of Protests")**
- **Provision for flexible response time for office actions**
  - Maximum response time would remain six months
  - Shorter times could be prescribed by regulation
  - Procedure would likely be similar to that for response to office actions during patent prosecution

Trademark Proposals – Post Registration

- **Expungement as ground for cancellation**
  - Director can institute an expungement proceeding
  - Proceeding would be based on a written request for expungement
  - Expungement would only be possible after three years from issuance for registrations issued under Section 44(e) (based on foreign registration) and Section 69 (registration based on Madrid Protocol)
  - Expungement is different from existing procedure where mark was once used but has since been abandoned

Trademark Proposals – Post Registration

- **Reexamination where mark has never been used**
  - Allow for reexamination of issued registrations in response to credible allegations that mark has never been used
  - Successful reexamination would result in registration being expunged
  - Expungement would only be possible after three years from issuance for registrations issued under Section 44(e) (based on foreign registration) and Section 69 (registration based on Madrid Protocol)
  - Expungement is different from existing procedure where mark was once used but has since been abandoned

Trademark Proposals – Post Registration

- **Cancellation for lack of reasonable care in verifying use**
  - an additional ground of cancellation would be added to Section 14(3),, namely, (1) there was a material false statement or representation regarding a claim of use in the underlying application, and (2) reasonable care was not exercised by the declarant in determining the veracity of the statement or representation.

Trademark Proposals – Post Registration

- **Establishment of rebuttable presumption of irreparable harm upon proof of infringement**
  - Provision would apply to both preliminary and permanent injunctions
  - This was the practice before the Supreme Court's *eBay* decision
  - Since eBay some courts have continued this practice but others have not