NYIPLA
The New York Intellectual Property Law Association®

BOARD OF DIRECTORS

OFFICERS

PRESIDENT
Kathleen E. McCarthy
1.212.556.2345
kmccarthy@kslaw.com

PRESIDENT-ELECT
Colman B. Ragan
1.973.658.1800
colman.ragan@tevapharm.com

1st VICE-PRESIDENT
Robert M. Isackson
1.914.821.1686
isackson@leasonellis.com

2nd VICE-PRESIDENT
Heather M. Schneider
1.212.728.8685
hschneider@willkie.com

TREASURER
Abigail Langsam
1.212.836.7836
abigail.langsam@arnoldporter.com

SECRETARY
Dyan Finguerra-DuCharme
1.212.326.0443
dfinguerra-ducharme@pryorcashman.com

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IMMEDIATE PAST PRESIDENT
Peter G. Thurlow
1.212.413.2832
pthurlow@polsinelli.com

NYIPLA EXECUTIVE OFFICE
2125 Center Avenue, Suite 406
Fort Lee, NJ 07024-5874
Tel: 1.201.461.6603
Fax: 1.201.461.6635
E-Mail: admin@nyipla.org
Website: www.nyipla.org

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NYIPLA Whitepaper
Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019 (the "BLOCKING Act of 2019")

(H.R. 938)

About the NYIPLA:

The New York Intellectual Property Law Association ("NYIPLA" or "Association") is a bar association of more than 1,000 attorneys who practice in the area of patent, copyright, trademark, and other intellectual property ("IP") law. It is one of the largest regional IP bar associations in the United States. The Association's members include a diverse array of attorneys specializing in patent law, from in-house counsel for businesses that own, enforce and challenge patents, to attorneys in private practice who represent businesses in such endeavors, as well as attorneys who represent inventors and petitioners in various proceedings before the United States Patent and Trademark Office.

A substantial percentage of the Association's member attorneys participate actively in patent litigation, representing both patent owners and accused infringers. In addition, many of the NYIPLA's member attorneys are involved in inter partes review ("IPR") and other post-issuance proceedings at the PTAB, on both sides of patent validity issues.

The NYIPLA thus brings an informed perspective to the issues of concern in this proposed legislation. The NYIPLA, its members, and their respective clients share a strong interest in ensuring a fair and predictable system fostering innovation and patenting for all stakeholders.

Bill Summary:

House Report 116-46 describes **H.R. 938** as designed to "discourage parking of 180-day exclusivity by a first generic applicant" by allowing the FDA to approve a subsequent generic application prior to the first applicant's first date of commercial marketing 180 days after the following four conditions are met: "(1) the subsequent application is ready for full approval; (2) a minimum of 30 months has passed since at least one first applicant submitted their application for the drug; (3) *any related patent litigation has been fully resolved by at least one first applicant*; and (4) no first applicant has received final approval." The relevant text of the bill matches this description except with respect to the 3rd condition, as shown below (compare text in italics):

> "(aa) The approval of such an application could be made effective, but for the eligibility of a first applicant for 180-day exclusivity under this clause.
>
> (bb) At least 30 months have passed since the date of submission of an application for the drug by at least one first applicant.

(cc) *Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).*

(dd) No application for the drug submitted by any first applicant is approved at the time the conditions under items (aa), (bb), and (cc) are all met, regardless of whether such an application is subsequently approved."

NYIPLA Concerns:

This bill will diminish the value of the 180-day exclusivity available to first-filers of ANDA Paragraph (iv) patent challenges because it introduces very substantial uncertainty in attaining that incentive. Clause (iii) cited in condition (cc) permits FDA to grant final approval once the 30-month stay has expired even if the litigation is not yet resolved. This bill could cause forfeiture while a first-filer is still in litigation, or has settled and applied for final approval while awaiting the settlement date for market entry. The uncertainty is heightened because first filers will not have advance notice of a subsequent filer's request for approval under this bill. In the MMA, Congress approved six forfeiture provisions that have been effective in reducing exclusivity parking; the evidence in the record is that such "parking" has not been a major occurrence since then, making the downside of the bill outweigh its upside. (The MMA is the Medicare Prescription Drug, Improvement, and Modernization Act, signed into law on December 8, 2003.)