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

MEMBERS
Douglas R. Nemec
Irena Royzman
Marian Underweiser
John T. Moehringer
Robert J. Rando
Alicia A. Russo
Patrice P. Jean
Gene W. Lee
Marc J. Pensabene

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

July 31, 2019

NYIPLA Whitepaper
"Terminating the Extension of Rights Misappropriated Act of 2019" ("TERM ACT of 2019")
(H.R. 3199)

About the NYIPLA:

The New York Intellectual Property Law Association ("NYIPLA" or "Association") is a bar association of approximately 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:

The TERM Act would create a presumption in any Hatch-Waxman or BPCIA proceeding in which the validity of an asserted patent is challenged 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) unless the patentee can prove by a preponderance of the evidence that the second patents are "patentably distinct" from the "first patent."

NYIPLA's Concerns:

NYIPLA is opposed to this bill in its current form and has several concerns as outlined below.

First, the NYIPLA is concerned that this bill does not clearly define the term "first patent" such that a patentee would be on notice as to which patent is to be used as a measuring stick for patent term.

Second, this bill also 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. This is especially concerning because all patents, including subsequent patents in a patent family, have been thoroughly examined by the USPTO prior to issuance and assertion and the USPTO should be presumed to have made a determination that any subsequent patent is "patentably distinct" from the prior art, including the "first patent." By disclaiming term and presuming a newly issued patent to not be "patentably distinct" from a so-called "first patent," this bill directly conflicts with 35 U.S.C. § 282, which imbues a patent issued by the USPTO with a presumption of validity.

Third, the bill also could substantially complicate patent litigation, where, in one proceeding, two different presumption standards could apply – one associated with listed biopharmaceutical patents relating to the approved product, and another presumption associated with patents in suit that are not listed.

Fourth, the presumed disclaimer of patent term could lead to challenges that provisions in the proposed legislation violate the Fifth Amendment's Takings Clause, and those sorts of challenges could cause considerable uncertainty for biopharmaceutical patentee innovators, as well as for companies wishing to market generics and biosimilars of the innovators' products.

Accordingly, for all of these reasons, the NYIPLA is concerned that this bill will effectively limit innovation in the biopharmaceutical arts to the first basic patent on the active ingredient and discourage additional innovation and/or investment in the biopharmaceutical arts (e.g., into new ways to deliver a drug to a patient and new uses/cures with a particular active ingredient).

In addition, Congress will need to evaluate this bill for compliance with international treaties. In its present form, this bill seems to create a rule similar to the judicial doctrine of "obviousness-type double patenting"[1] but specifically targeting only biopharmaceutical patents with an evidentiary presumption *against* the patentee – a reversal of the general rule that "obviousness-type double patenting" is an affirmative defense that a patent challenger must support with clear and convincing evidence.[2] The NYIPLA believes that treating patents related to any specific technology differently from patents in other technologies would change U.S. patent law in a manner that conflicts with the U.S.'s obligations under the TRIPS treaty.

[1] See, e.g., *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), and *Abbvie v. Mathilda & Terence Kennedy Institute*, 764 F. 3d 1366 (Fed. Cir. 2014)

[2] *See, e.g.*, *UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313, 1323 (Fed. Cir. 2018).