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The New York Intellectual Property Law Association®

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NYIPLA Whitepaper
Pay-for-Delay Settlement Legislative Proposals

[H.R. 1344, 1499, 2375; S. 64]

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, including on both the "brand" and "generic" side of pharmaceutical patent disputes. 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.

Bills Summary:

Four pending bills (3 House, 1 Senate) impose, and authorize the FTC to enforce, restrictions on the terms of patent litigation settlements in which an ANDA filer or a biosimilar biological product application (BBPA) filer (i) receives anything of value, including non-cash items such as a patent license (*See* H.R. 1499) or an exclusive license (*see* S. 64), and (ii) the ANDA filer or BBPA filer agrees to limit or forgo research, development, manufacturing, marketing, or sales of the ANDA product or biosimilar biological product, as applicable, for any period of time. These bills render presumptively anticompetitive agreements containing provisions (i) and (ii) (the presumption is explicit in H.R. 1344, H.R. 2375, and S. 64, and implicit in H.R. 1499). Under H.R. 1344, H.R. 2375, and S. 64, a party can rebut the presumption by clear and convincing evidence that the value received is compensation solely for other goods or services that the ANDA/BBPA filer has promised to provide; or that the procompetitive benefits of the agreement outweigh its anticompetitive effects. H.R. 1499 limits rebuttal to clear and convincing evidence that the compensation is solely for other goods or services that the ANDA or BBPA filer has promised to provide.

Under all 4 bills, a settlement agreement may include a provision to compensate the

ANDA/BBPA filer for its reasonable litigation expenses not to exceed $7,500,000. Under some of these bills, including S. 64, a settlement may also include (1) the right to market the ANDA/BPPA product prior to the expiration of any patent that is the basis for the patent infringement claim, or any patent right or other statutory exclusivity that would prevent marketing of the product; and (2) a covenant not to sue on any claim that the ANDA/BPPA product infringes a U.S. Patent.

All four bills would mandate payment of a civil penalty capped at three times the value received by, or given to the ANDA/BBPA filer that is reasonably attributable to the violation. Two bills (H.R. 1344 and S. 64) would apply the settlement term restrictions retroactively to agreements made after June 17, 2013, but not the civil penalty. H.R. 1499 and H.R. 2375 would apply only prospectively.

NYIPLA Concerns:

NYIPLA is opposed to these bills in their current form. However, as discussed below, we think a unified federal approach to address these issues is greatly preferable to a state-by-state approach.

Contrary to their intended purpose and goal, these bills will have the unintended and undesirable effect of *prolonging* the period before lower-cost pharmaceuticals and biosimilars come on the market. They will discourage settlement and thus compel more parties to litigate these patent cases to the bitter end. Current statistics suggest that more than 50% of the Hatch-Waxman pharmaceutical cases that go to trial result in at least one patent claim being found valid and infringed, meaning that, absent settlement, the public must wait until expiry of such patent for the entry of a lower-cost medication. If parties face increased risk from settling each individual case, they are likely to make fewer challenges to fewer patents before expiration to offset the cost and risk of having to litigate more cases all the way through to trial. The consequence of this is that only the cases having the weakest patents will be challenged, and thus overall fewer generic drugs will come on market before the patent expiration.

The main reason for this unintended effect is that all four bills set a more stringent legal standard for the scope of a permissible patent litigation settlement agreement than did the U.S. Supreme Court in *FTC v. Actavis*. The Court declined to hold pay-for-delay (aka reverse payment) settlement agreements presumptively unlawful, in favor of a rule of reason analysis that allows balancing of pro-competitive and anti-competitive effects. The rule of reason approach makes sense given that these disputes sit at the intersection of patent law, FDA regulatory and antitrust issues, and must balance private property and contracting rights, public policy, and governmental interests. In contrast, these bills make almost all settlement agreements presumptively anticompetitive and limit their permissible content to very few types of provisions. This heightened standard is even more concerning in view of (a) the mandatory and substantial civil penalty the bills will impose, and (b) the retroactive application of H.R. 1344 and S. 64 to agreements made under the guidance of *FTC v. Actavis*. Retroactive application of these bills could have additional consequences, such as including (i) clogging court dockets with once-resolved patent litigations and brand new antitrust litigation and (ii) causing the removal of medications from the market because parties are unwilling to face the prospect of retroactively imposed punitive damages or and willful patent infringement liability and (iii) potential challenges under the Takings Clause of the Fifth Amendment. Given the statutory presumptions, the limited permissible terms, and the mandatory penalty, these bills leave the parties with little left to negotiate in settlement and big downside risks if they do so.

NYIPLA also questions the need for this legislation now, in view of the positive impact of *FTC v. Actavis*. The Federal Trade Commission issued a statement on

May 23, 2019, that while brand and generic drug makers settled patent disputes more often in fiscal year 2016 (the most recent year for which FTC has reported data) than prior years, only one of the agreements met the Supreme Court's criteria for potentially being anticompetitive.

An additional concern is that 3 of these bills raise a question regarding the evidentiary standard on appellate review, i.e., they contain the following provision: "TREATMENT OF FINDINGS.—In a proceeding for judicial review of a final order of the Commission, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive. "See H.R. 1344, H.R. 2375, and S. 64. It is unclear whether this language lowers the appellate standard for deference to FTC findings to something less than the substantial evidence test that exists in current case law. This ambiguous standard will create further confusion and litigation over its meaning and potential constitutional challenges (procedural due process and separation of powers).

Although the NYIPLA opposes the settlement bills in their current form, we recognize the need for federal legislation in this field so long as concerns like the foregoing are addressed. We believe federal legislation is far preferable to a patchwork-quilt approach in which individual states could impose their own restrictions on pay-for -delay settlements. The bill recently passed in California (Assembly Bill 824 ("Cal. 824")) illustrates this issue.

Like the pending federal legislation, Cal. 824 would render presumptively anticompetitive an agreement under which a "nonreference drug filer" (e.g. a generic drug company) receives "anything of value" from a patent holder in exchange for an agreement to limit or forgo research, development, manufacturing, marketing, or sales of the nonreference drug filer's product. Cal.824 identifies several exceptions to the definition of "anything of value."

However, the penalties for violation (i.e. for failure to overcome the presumption of an anticompetitive effect) are Draconian. Specifically, each person that violates or assists in the violation of the law shall be subject to the following penalties:

(i) If the person who violated this section received any value due to that violation, an amount up to three times the value received by the party that is reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater.

(ii) If the violator has not received anything of value as described in clause (i), an amount up to three times the value given to other parties to the agreement reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater.

The law does not define "person," meaning that a company executive, counsel, accountant or other individual could be subject to these extreme penalties. This would undoubtedly severely discourage anyone from attempting to settle pharmaceutical patent case.

In addition to the general concerns expressed above with respect to pay-for-delay settlement bills in general, the enactment of Cal. 824 creates a separate statutory scheme that must be complied with for all drugs sold into California—which is all of them. If other states likewise adopt their own pay-for-delay settlement bills, then the compliance task for branded and generic companies alike could become unmanageable. Accordingly, the NYIPLA believe that Congress should enact a reasonable pay-for-delay settlement bill, which would set a uniform, national standard, compliance with which would be sufficient across all fifty states.