May 11, 2023

NYIPLA Whitepaper
New York State Biopharmaceutical Settlement Legislative Proposals

[A. 895/S. 3518; S. 4513]

About the NYIPLA:

The New York Intellectual Property Law Association ("NYIPLA" or "Association") is a bar association of approximately 700 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.

Bill Summary:

This whitepaper addresses a proposal related to patent settlements that has been presented as part of Governor Hochul's Executive Budget for New York state as well as in standalone bills before the legislature, including A. 895 and S. 3518.[1]

These proposals would require the manufacturer of a "brand name" prescription drug to report any arrangement (through agreement or otherwise) with another manufacturer that "has the purpose or effect of delaying or preventing such other manufacturer from introducing a generic substitute for such drug into the marketplace." The brand-name drug manufacturer would have 30 days to report such arrangement to the Attorney General,[2] with a notice that includes the drug name, wholesale price, disease for which such drug is commonly prescribed, name of manufacturer, name of generic manufacturer, and "the length of the delay." § 396-rrr (1)(a). The Attorney General would then have 30 days to provide notice of the filing to the drug utilization

[1] A. 3007/S. 4007 Executive Budget Proposal, Health and Mental Health Article VII, Part Y, Subpart B, section 3005.

[2] Note that the Executive Budget proposal substantively mirrored A. 895/S. 3518, but would instead require disclosure to the Department of Financial Services. That proposal also would have required disclosure to the Drug Accountability Board housed in the Department.

review board and all Medicaid managed care plans, health plans and pharmacy benefits managers. § 396-rrr (1)(b). In addition, the Office of the Attorney General would post all of the notices on its website in a searchable format. § 396-rrr (2). Manufacturers that knowingly or negligently fail to provide the required notice can be fined $5,000 per day for the first infraction and $10,000 per day for subsequent violations.

We understand that A. 895/S. 3518 differ significantly from NY Senate Bill 4513, entitled "Preserving Access to Affordable Drugs," which would create a presumption that settling a patent infringement claim in connection with the sale of a pharmaceutical product has anticompetitive effects in certain circumstances where the nonreference drug filer "receives anything of value" or agrees to limit or forego R&D, manufacturing, marketing or sales of the nonreference drug. Violators would pay a penalty to the state of three times the value exchanged under the agreement or $20 million, whichever is greater, as well as possible damages under the state general business law and executive law. § 298(5)(a)-(b). This is similar to a California law (CA AB 824), which was passed in 2019. The constitutionality of AB 824 was challenged soon after, and in February of 2022 a court limited the scope to "settlement agreements negotiated, completed, or entered into within California's borders." *Ass'n for Accessible Medicines v. Bonta*, No. 2:20-CV-01708-TLN-DB, 2022 WL 463313, at *8 (E.D. Cal. Feb. 15, 2022).

NYIPLA is concerned that, because A. 895/S. 3518 may be seen as more legally sound and less draconian alternatives to S.B. 4513, NY State legislators and the Governor may be more inclined to support these proposals. NYIPLA believes that would be a critical mistake, as NYIPLA has significant concerns about these proposals, as discussed below. (NYIPLA is opposed to S.B. 4513 as well, but given the legal challenges to CA AB 824, views that bill as a less likely option for serious consideration by the New York State legislature at this time.)

NYIPLA Concerns:

NYIPLA is opposed to A. 895/S. 3518 in substance and because a unified federal approach to address these issues is greatly preferable to a state-by-state approach.

First, it is not clear what authority the Attorney General has to share confidential information about patent settlements with other entities, such as the drug utilization review board, or to post such information on a public website. While the goal of these proposals may be to deter anticompetitive conduct, it is not clear that goal is advanced by having the Attorney General distribute and post information that is not related to an ongoing investigation and has not been shown, or even alleged, to be anticompetitive.

Second, if the goal of these proposals is to reduce drug prices by preventing settlements that delay competition, they will not satisfy that goal unless they clearly define what is meant by "delay." For example, the Office of the Attorney General may consider that any settlement that allows entry later than the generic manufacturer could have won in a lawsuit by proving invalidity or noninfringement of every patent is a "delay." In that scenario, manufacturers would have no incentive to settle at all. They have nothing to gain by settling rather than fighting the patent case to the bitter end. Publicly available statistics show that patent holders win substantially more than 50% of the patent infringement cases involving pharmaceutical patents. This number is even higher for cases tried under the Hatch-Waxman framework. Thus, neither scenario will achieve the goal of lowering prices by faster entry of generic and biosimilar drugs.

Third, under these proposals, parties on both sides of the litigation will be dissuaded from settling because of confidentiality concerns. These proposals require the Office of the Attorney General to publish the notice on a website and distribute it to all pharmacy benefit managers and others. It is unclear whether the Attorney General will require parties to submit the full settlement agreement. The parties then will be vulnerable to antitrust suits, and their competitors may learn their highly confidential business terms. Because there will be fewer out-of-court resolutions of these commercial disputes, the Federal Court system (including the Federal Courts in New York State), will have backlogs of patent cases, which will result in a significant increase in the caseloads for the Federal Judiciary, including New York judges.

NYIPLA also questions the need for these proposals now, in view of the positive impact of the Supreme Court's decision in *FTC v. Actavis*. The Federal Trade Commission issued a statement on December 3, 2020, that, although the number of settlements entered by pharmaceutical companies in Hatch-Waxman cases in FY 2017 was close to the record high in FY 2016, those that include reverse payments remain very low. And, for the first time since FY 2004, no settlement agreement contained a commitment not to market an authorized generic. [3]

If such legislation were helpful, we believe federal legislation would be far preferable to a patchwork approach in which individual states attempt to impose their own restrictions on so-called pay-for-delay settlements. The bill recently passed in California, AB 824, illustrates this issue, as it now provides a unique requirement that only applies to settlements entered in California.

In the end, if anything is to be done to alleviate the purported harm with "pay for delay" settlements, NYIPLA believes that Congress should enact a reasonable bill that would set a uniform, national standard, to affect uniform compliance across all fifty states.

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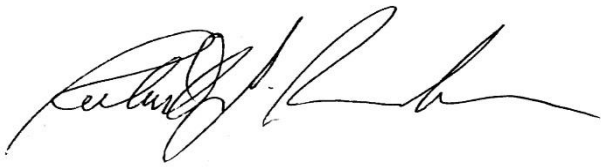
Sincerely,



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[3] FTC Staff Issues FY 2017 Report on Branded Drug Firms' Patent Settlements with Generic Competitors, https://www.ftc.gov/news-events/news/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent-settlements-generic-competitors (last visited Apr. 19, 2023).