WEBINAR

What IP Lawyers Need to Know About California's New Reverse Payment Law

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Webinar Guidelines

- Participants are in listen-only mode
- Submit questions via the Q&A feature
- Questions will be answered as time permits
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The Statute (in a nutshell)

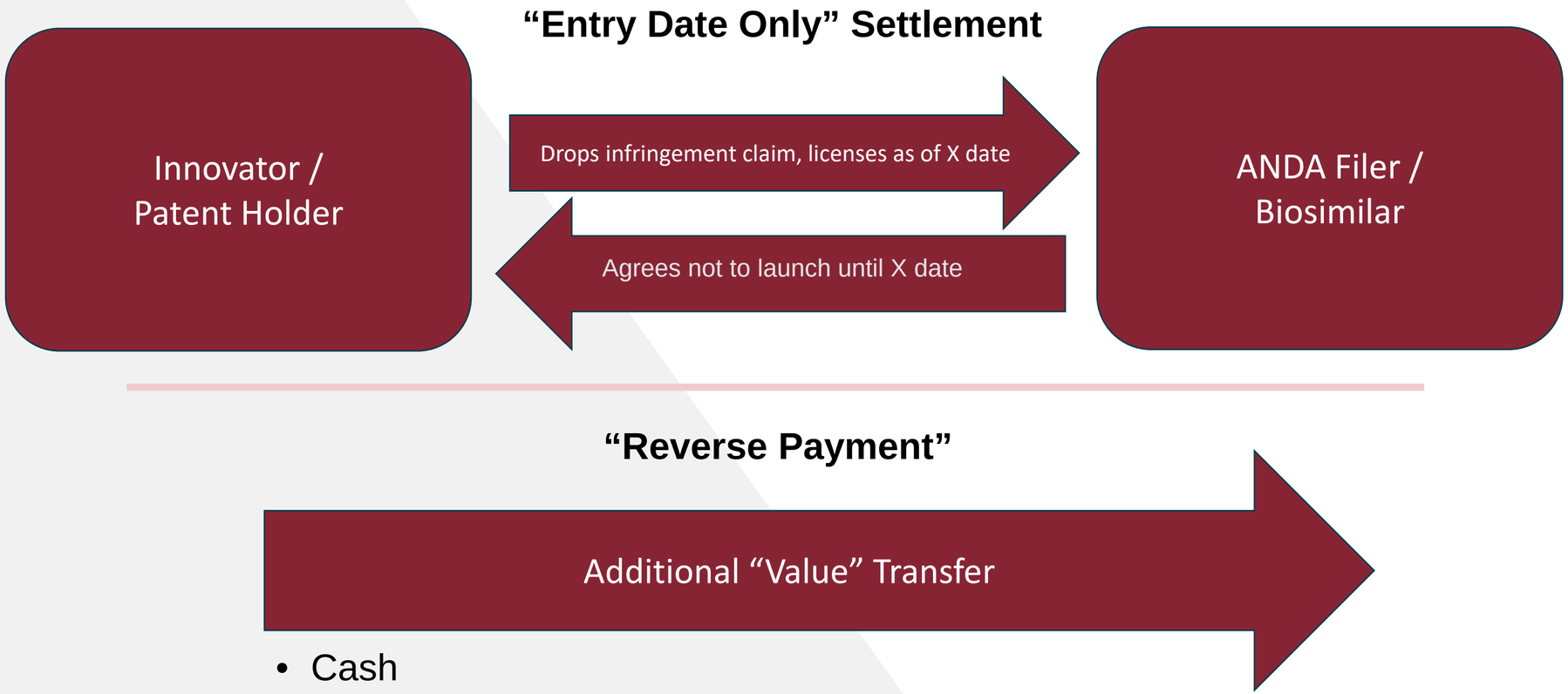
AB-824 “Preserving Access to Affordable Drugs”

- Sponsored by California Attorney General Xavier Becerra
- Signed October 17, 2019, effective January 1, 2020
- Targets so-called “reverse-payment” or “pay for delay” settlements of ANDA litigation and biosimilar litigation
- Creates a presumption that “reverse payments” (with few exceptions) are anticompetitive
- Limits ways defendants can try to rebut presumption of anticompetitive effect, requiring certain presumptions (favorable to state) and prohibiting others (that would benefit defendant)
- Imposes severe penalties—minimum $20 million—for each person that “violates or assists in violation of this section” (in addition to liability in private actions)
- Four-year statute of limitations
- Reaches all settlements implicating drugs sold in California, not just those between California companies or entered into in California (although this reach is subject to challenge)

What you need to know (in a nutshell)

1) More restrictive than *Actavis* in terms of burdens on defense, increasing risk of settlements that include value transfer
2) Places rigid limits on litigation cost avoidance payments that did not previously exist under federal law
3) Attorney General increasing enforcement resources, and signals potential efforts to challenge the attorney-client privilege and common interest privilege when defendants try to meet their burdens
4) Preliminary constitutional challenge at district court level unsuccessful, and motion to stay pending appeal has been denied. Ninth Circuit appeal pending.

What is a "Reverse Payment"?



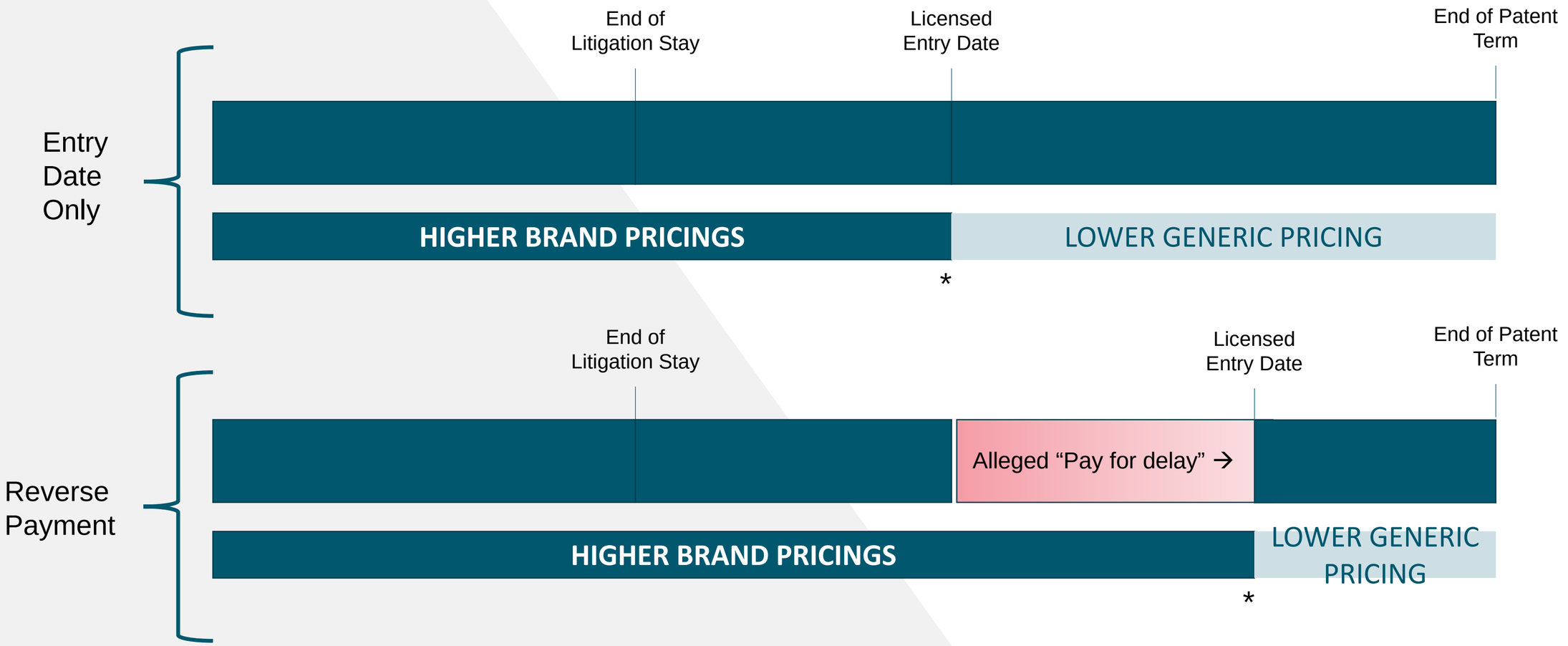
- Cash
- Payments for goods/services provided by generic
- Agreement to forgive debt (other litigation liability)
- Agreement not to compete by launching an "authorized generic"

Why do competition enforcement authorities care?

Reverse payment analysis based on FTC's "probabilistic patent" theory

- Likelihood of patent claims succeeding corresponds to "patent strength" (e.g., 50%)
- Patent strength corresponds to expected level of competition (e.g., half of remaining patent life)
- Expect level of competition is benchmark for analyzing competitive impact of settlement (i.e., does the settlement entry date provide for more or less competition?)
- Absent payment, agreed entry date should be fair approximation of patent strength
  - According to FTC, but not quite (asymmetric risks, royalties)
- "Delay" in entry-date-only settlement reflects strength of patent (immune)
- Additional payments to the challenger likely move settlement entry date out, buying more freedom from competition than strength of the patent earns, maintaining higher brand prices longer

Why do competition enforcement authorities care?



FTC v. Actavis (June 2013)

"Reverse payments" may be anticompetitive

- So-called "rule of reason" balancing test applies
  - Rejected FTC position on appeal that reverse payments be deemed presumptively anticompetitive (so-called "quick look")
- "Large, unexplained" payments may trigger antitrust scrutiny
- Certain types of payments do not raise competitive concerns
  - "Fair value" for goods and services
  - Litigation cost avoidance—payments that reflect the patentee's saved costs in not having to litigate patent rights to judgment (more later on this)
- Was an FTC Section 5 claim, so Supreme Court did not confront whether there are additional requirements for private litigants seeking damages (causation)

After Actavis

There has been confusing, often conflicting application by lower courts

- Plaintiff's *prima facie* burden:
  - To show "large, unexplained" payment
    - Includes anything of value, not just cash (e.g., no-AG agreement)
    - Not "fair value" (unclear whether that is complete defense, and some treat it as an affirmative defense for which the burden is on defendants)
    - Greater than litigation cost avoidance ("large")
  - To show market power (*e.g.,* the "relevant market" is the drug and generic versions)
- Defendant then may proffer procompetitive benefits
- Plaintiff's ultimate burden to show such benefits are pretext, could be achieved through less restrictive means, or agreement was on balance anticompetitive
- In private claim for damages, plaintiff must also prove that plaintiff suffered losses as a result of the reverse payment (may implicate patent merits)

California Application

In re Cipro I & II (Cal. 2015)

- 2015 Supreme Court of California decision applying Cartwright Act
- Plaintiff's burden:
  - To show payment and delay
- If defendants proffer evidence of litigation costs and goods/services from generics, then plaintiff has burden of showing payments not fair value / exceed litigation costs
  - Doing so would allow presumption of market power
- Defendant then may show procompetitive benefits
- Plaintiff's ultimate burden to show agreement was on balance anticompetitive

California's AB-284

- Any patent settlement with ANDA or biosimilar* applicant "shall be presumed to have anticompetitive effects" and shall be a violation of this section if:
  - Generic receives "anything of value" (payment); AND
  - Generic agrees to limit/forgo R&D, manufacture, or sale for any period of time (delay)
  - *Silent as to agreements with 505(b)(2) applicants
- Penalties
  - Fine, the greater of $20 million or:
    - If violated received value – up to 3x value received "reasonably attributable to the violation"
    - Otherwise – up to 3x value given to others "reasonably attributable to the violation"
    - "value attributable to the violation" determined by California share of market for brand drug
  - Also potential liability under Cartwright Act or Unfair Competition Law

California's AB-284

"Anything of value"

- Expressly <u>includes</u> "exclusive licenses" and no-AG provisions (codifying *Lamictal*)
- Expressly EXCLUDES (meaning the following are NOT "reverse payments"):
  - "Early entry"—The right to launch before expiration of patent(s)-in-suit or any other patent or statutory exclusivity that would prevent marketing of drug
  - A covenant not to sue from the brand to the generic
  - Litigation cost avoidance (subject to conditions, more later)
  - An acceleration provision that allows the generic to launch earlier if the branded company "seeks approval to launch, obtains approval to launch, or launches" a product line extension
  - Agreement not to interfere with generic's regulatory approval process
  - Forgiving damages for generic's entry at risk for <u>that</u> drug

California's AB-284

"Agreement resolving or settling a patent infringement claim" includes:

- Any agreement that is entered into within 30 days of the resolution or the settlement of a claim; or
- Any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim
  - (Mirrors scope of FTC/DOJ filing requirements under Medicare Modernization Act)

#1
Impact on Litigation / Risk Evaluation

California's AB-284

Overcoming the presumption

- Settling parties have the burden of proving, by preponderance of the evidence
  - That payments were "fair and reasonable compensation solely for other goods or services provided"
  - The agreement "directly generated procompetitive benefits" AND "the procompetitive benefits … outweigh the anticompetitive effects of the agreement"
- In assessing procompetitive benefits, the factfinder shall not presume:
  - "Early entry" makes it procompetitive
  - That any patent is enforceable or infringed absent final adjudication
  - That the agreement caused no delay because of lack of FDA approval (*Nexium)*
  - That the agreement caused no delay because the generic might infringe some other patent (*Wellbutrin*)
- Senate amendment allows these findings based on "full scope of the evidence"

California's AB-284

Market definition presumption

- In determining whether settling parties have met their burden…
  - The factfinder "shall presume" that the relevant product market is that market consisting of the brand and generic versions (bioequivalent or biosimilar)
- Almost assures a finding of market power
- Means settling parties will be unable to defend claims by arguing that availability of similar treatments limit anticompetitive effects of delay
- Sponsor claimed that would "prevent prolonged and expensive litigation over definition of the relevant market"
  - Cited *Endo* and *Opana* cases where market was litigated but court found for government
  - *But see* cases like *Doryx* in which courts found broader relevant markets

#2
Litigation Cost Avoidance

Litigation Cost Avoidance (LCA) Defined

- The FTC characterizes LCA as "compensation for saved future litigation expenses" (*See* FTC-Cephalon Consent Order, at ¶ 38(a))
  - LCA is a payment from the patentee to the generic challenger that is less than or equal to the brand's expected saved litigation costs realized due to the settlement
    - Including attorneys' fees, expert fees, other costs and expenses
- LCA is not the generic challenger's sunk cost of litigating
  - Generic companies often confuse this in negotiations
- The Supreme Court in *Actavis* has expressly recognized LCA as an exception:
  - "The reverse payment, for example, **may amount to no more than a rough approximation of the litigation expenses saved through the settlement**. …. Where a reverse payment reflects traditional settlement considerations, **such as avoided litigation costs** …, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement."

The FTC's Position and Rationale

The FTC itself has long recognized that LCA payments do not cause anticompetitive harm:

- In early Commission decisions, including *Schering-Plough*, the Commission's consent orders allowed payments to the generic if the payments were "less than $2 million or expected litigation cost" (*See Schering-Plough*, at n.69)
  - Some practitioners considered this a $2 million "safe harbor," but FTC has never clearly deemed $2 million as a safe harbor
- More recent orders (e.g., *Cephalon*) allow for "compensation for saved future litigation expenses … that does not exceed … [$7 million]" (with the $7 million to be adjusted annually for inflation)
  - Conservatively, this implies that the amount must be no greater than the lesser of (1) actual saved litigation costs, or (2) $7 million as adjusted
  - This is the conservative standard we often apply

The FTC's Position and Rationale

The FTC explained its position to the Supreme Court in *Actavis*:

> "Second, the [settling parties] could rebut the presumption [that a brand payment was anticompetitive] by showing that the payment was commensurate with the litigation costs that the brand name manufacturer avoided by setting. Because such a payment is most naturally understood to reflect the parties' agreed division of their savings from avoiding litigation, **it does not suggest that the compromise date of generic entry specified in the settlement reflects anything but the parties' true assessment of the merits of litigation.**" Br. of FTC, *Actavis*, at 38

A group of influential economists in "Activating *Actavis*" similarly explained:

> "The patentee is willing to pay an amount up to litigation costs to get as much protection from competition as it expects to get from litigation."

AB-284 on Litigation Cost Avoidance

Compensation for saved reasonable future litigation expenses of the brand do not fall within the definition of “anything of value”

But only if:

- The saved litigation expenses are documented in budgets at least six months before the settlement
- The compensation does not exceed the lower of:
  - $7.5 million
  - 5% of the revenue the generic forecasted for its first 3 years of sales documented at least 12 months before the settlement.
    - If no documented forecasts, $250,000

AB-284 on Litigation Cost Avoidance

Guidance

- Budget early and revise as necessary
  - Attorney's fees and costs, as well as expert fees (and other expenses)
  - Increase budgets promptly when developments increase likely costs
- Seek proffer of actual forecasts from generics for LCA in excess of $250,000
  - $250,000 would equal three year forecast of one of five generics to enter against a branded drug with annual sales of <u>about $1.85 million</u>
    - (Assuming 90% brand share loss to generics, 75% price erosion, and 20% generic share)

#3
Enforcement

Enforcement

California AG has been active in reverse payment enforcement

- July 2019 - $70M settlement of “reverse payment” claims against Teva (Provigil) and Teva, Endo, and Teikoku (Lidoderm)
- Heightened rhetoric and commitment to enforce aggressively
  - AG Becerra: “These dark, illegal, collusive agreements that drug companies devise…”
  - AG Becerra: “These pay-for-delay arrangements are kept secret…”
- Claims new law allows California to be a “leader in pay-for-delay litigation”
  - According to legislative history, plans to spend an additional $1-2M per year on staff (including 3 new AAGs), experts, and other litigation costs to pursue investigations

Enforcement

Implications for Attorney-Client and Common-Interest Privileges

- Attorney General Xavier Becerra (co-sponsor):
  - Upon introduction: “AB 824 would … prevent the parties from withholding relevant evidence regarding the agreements behind attorney-client and common-interest privileges.”
  - Upon passage: “The new law … would also limit the ability of drug companies to use attorney-client and common-interest legal privileges to withhold relevant evidence”
- No provision of AB 824 speaks to discovery or privilege
- Likely foreshadowing argument that efforts to meet defendants’ burden under AB 824 will put attorney-client communications “at issue”
  - Compare *King Drug v. Cephalon,* where repeated attempts to pierce the defendants’ privilege failed because Court found no at-issue waiver
  - California law recognizes only limited “at-issue” waiver (if substance of communication is tendered in issue by privilege holder, not merely because it is one of several forms of indirect evidence)

#4
Constitutional Challenge

Constitutional Challenge

In November 2019, Association for Accessible Medicines (AAM), a generics trade organization, brought suit to enjoin:

- Principal argument—violates "Dormant" Commerce Clause by regulating settlements entered into outside of California and/or between/among non-California entities
- On December 31, 2019, District Court (E.D. Cal.) denied the preliminary injunction motion, allowing the law to go into effect.
  - The statute was not facially invalid because it could be applied in a way that plaintiffs acknowledge would not violate Commerce Clause (intra-state conduct)
  - Otherwise, challenge was not ripe because plaintiff could not show that it was likely to be unlawfully enforced or that the threat of enforcement has dissuaded any party from acting in a way that would violate the law.
- Decision has been appealed to the Ninth Circuit
  - Application for stay pending appeal denied

Questions

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- Partner, Boston, Antitrust Litigation
- Litigates matters and counsels clients on antitrust issues arising from:
  - Settlements
  - Sham litigation and *Walker Process* fraud
  - Life cycle management and “product hopping”
  - REMS and SSRS issues
  - Orange Book listings
  - Product bundling and loyalty discounts