WELCOME

Reverse-Payment Patent Settlements
Do they have a future?

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Welcome!

- You are on mute
- A link to a recording of the webinar will be made available
- We will not take questions as we go along but should have some time to take questions at the end of the session
The Speakers

Simon Uthmeyer
Partner, DLA Piper
Sydney

Bertold Bär-Bouyssière
Partner, DLA Piper
Competition Law
Brussels

Carl Hittinger
Partner, DLA Piper
Anti-Trust
Philadelphia

Paolo Morante
Partner, DLA Piper
Anti-Trust
New York

Stuart E. Pollack
Partner, DLA Piper
Patent Litigation
New York

Gualtiero Dragotti
Partner, DLA Piper
Patent Litigation
Milan

- Intended to foster competition by providing a simpler pathway to generic approval and encouraging generics to challenge (weak) pioneer patents before expiration.
  - Provides mechanism for early patent infringement litigation.
  - Stays generic approval process for 30 months following filing of lawsuit.
  - Grants first-to-file generic a six-month exclusivity following earlier of market entry or court ruling that underlying patent is invalid or not infringed.

- **But** creates “perverse” incentives...
  - Patent litigation presents little risk for generic, but significant risk for pioneer.
  - If first generic agrees to stay off market, operation of six-month exclusivity also keeps out all other generics.

- …leading to financially reasonable but unusual settlements:
  - Plaintiff (pioneer/patentee) pays defendant (generic/alleged infringer) to
    - End litigation without a ruling of invalidity or non-infringement; and
    - Stay off the market for a negotiated period, **which typically ends before patent expiration**.
Despite early victories, challenging reverse-payment settlements in the US has been an uphill battle.

FTC has been persistent, but courts have generally disagreed.

Prevailing approach pre-Actavis: the “scope of the patent” test

- Premised on presumption of patent validity and desire to avoid re-litigating that issue in an antitrust court.
- Reverse-payment settlement found lawful as long as the litigation is not sham, the underlying patent is not fraudulent, and the settlement’s anticompetitive effect does not exceed the exclusionary potential of the patent.

K-Dur (July 2012): Third Circuit takes radically different tack

- Reverse-payment settlements are presumptively illegal.

Circuit split leads Supreme Court to take up Actavis
CURRENTLY SPEAKING

**Federal Trade Commission v. Actavis, Inc. et al.** (June 17, 2013)

- Reverse-payment patent settlements under Hatch-Waxman Act must be analyzed under the **rule of reason**.
- Rejects prevailing scope-of-the-patent test.
- Rejects FTC’s presumption of illegality (or “quick-look”).
- Overriding concern with allowing pioneer and generics to **split monopoly profits** at the expense of consumers.
- Discourages revisiting patent validity.
  - “[T]he size of the unexplained reverse-payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”
- **Limited affirmative guidance** on how to apply the rule of reason
  - “[T]he likelihood of a reverse-payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”
- Attempts to cabin decision to settlements involving reverse **cash payment**...but proof of the pudding is in the eating.
Chief Justice Robert’s Dissent

- Joined by Justices Scalia and Thomas (Justice Alito did not participate);
- Highlighted the potential of majority’s decision to create novel and problematic issues for intellectual property litigants.
- Noted that the majority’s decision departed from existing law by holding for the first time that antitrust law can trump intellectual property law.
- Previewed how the majority’s decision could affect future intellectual property settlements and settlement agreements more broadly.
Overview of Reasons for the Dissent

- The majority’s decision holds for the first time that antitrust laws can be used to invalidate a patent right, even where the conduct at issue is within the scope of the patent.
- The majority’s decision undermines the traditional encouragement and protection courts give to settlement agreements by holding that a settlement can be disturbed on the basis of antitrust analysis.
- Even though the case before the Court involved only reverse-payment patent settlements, its effects could extend further and affect settlements in other contexts.
“The point of antitrust law is to encourage competitive markets to promote consumer welfare. The point of patent law is to grant limited monopolies as a way of encouraging innovation.” (Dissenting Op. 2)

“In doing so it provides an exception to antitrust law, and the scope of the patent – i.e., the rights conferred by the patent – forms the zone within which the patent holder may operate without facing antitrust liability.” (Dissenting Op. 2)

“We have never held that it violates antitrust law for a competitor to refrain from challenging a patent.” *Id.*
Potential for Encroachment of Antitrust Law on Patent Law

Under prior precedent, “a patent holder acting within the scope of its patent has an obvious defense to any antitrust suit: that its patent allows it to engage in conduct that would otherwise violate the antitrust laws.” (Dissenting Op. 4)

Under the majority’s ruling, however, the settling patentee “is not immunized by the fact that it is acting within the scope of its patent” (Dissenting Op. 11)

“Our cases establish that antitrust law has no business prying into a patent settlement so long as that settlement confers to the patent holder no monopoly power beyond what the patent itself conferred – unless, of course, the patent was invalid, but that again is a question of patent law, not antitrust law.” *Id.*
“The majority’s rule will discourage settlement of patent litigation.” (Dissenting Op. 11)

“Under [the majority’s] approach, a patent holder may be found liable under antitrust law for doing what its perfectly valid patent allowed it to do in the first place; its sin was to settle, rather than prove the correctness of its position by litigating until the bitter end.” (Dissenting Op. 14)

“[The majority today . . . likely undermines the very policy it seeks to promote by forcing generics who step into the litigation ring to do so without the prospect of cash settlements.” (Dissenting Op. 18)
Settlement agreements are supposed to be encouraged by the courts

“Ordinarily, we would think [settlement] is a good thing.” (Dissenting Op. 3)

Typically, courts seek to protect settlement agreements, not undermine them

Under the majority’s decision, settlement agreements are no longer sacrosanct because they can be scrutinized and invalidated on antitrust grounds

“I fear the Court’s attempt to limit its holding to the context of patent settlements under Hatch-Waxman will not long hold.” (Dissenting Op. 11)

While the decision is technically limited to the reverse-payment context, what it essentially says is that a settlement agreement in any context must be reviewed for potential anticompetitive effects
Practice Tips

Carl Hittinger
Partner, DLA Piper
Anti-Trust
Philadelphia

- Obtain court approval of your settlement agreements
- While settlement agreements submitted to the court will not be confidential, the risk may be worth taking because if the court places its imprimatur on the agreement, it may immunize the agreement from a later antitrust challenge
- Seek advice of antitrust counsel before agreeing to settle an intellectual property case, or any case that potentially involves competitive effects
- Work hand-in-hand with antitrust specialists when developing the specific terms of any settlement agreement
- Follow closely lower courts’ interpretation and application of the majority’s decision
"It is of course a longstanding topic of debate in economic and legal circles how to marry the innovation bride and the competition groom. In the past some have argued that such a marriage will unavoidably lead to divorce because of conflicting aims of IPR law and competition law. But I think that by now most will agree that for a dynamic and prosperous society we need both innovation and competition. Contrary to what some might think, competition is a necessary stimulus for innovation. IPR law and competition law have a complementary role to play in promoting innovation to the benefit of consumers. I therefore firmly believe in this marriage and, like in all good marriages, the real question is how to achieve a good balance between both policies."

Originator *versus* Generics

- Originator companies are most concerned with the strength of their position, i.e. the probability of winning or losing, as well as with the importance of the product for their overall business (turnover, market shares, presence of other market players, etc.).

- Generic companies are more concerned with saving costs arising from lengthy and complex litigation proceedings, as well as with removing the uncertainty inherent in patent litigation.
In the EU Pharma Sector Inquiry the Commission categorized settlement agreements that do not restrict the generics company's ability to market its own product as an A-type settlement.

Other settlement agreements, which limit generic entry, were categorized as B-type settlement.

Those settlement agreements which did not comprise a value transfer from the originator to the generics company were held to constitute B.I settlements.

B.II settlements entailed a value transfer from the originator to the generics company. These are the "reverse-payment patent settlements".
Reverse-payment settlement agreements are thus an agreement between patent owners and alleged patent infringers that involve a transfer of consideration from the patent owner to the alleged infringer.
Lundbeck (EU Decision 19 June 2013)

- Lundbeck's Citalopram – basic drug off patent 01/2002
- 2001-2002 Lundbeck obtains new process patents – in particular the crystallisation patent
- Lundbeck threatens generics with litigation
- Certainty of litigation
- Uncertainty of outcome
- September 2001 – "clearing the way" ruling in UK (Paroxetine)
- 01/2002 – reverse-payment settlement agreements

Bertold Bär-Bouyssière
Partner, DLA Piper
Competition Law
Brussels
In Lundbeck, the European Commission relies solely on the "restriction by object test"

In other cases, the European Commission and the OFT rely on
- The "restriction by object test",
- The "restriction by effect test", and on
- The "abuse of a dominant position test".
A restriction by object is typically a form of conduct that is of such an offensive nature, that its capacity to harm competition in the most serious manner may be presumed and an analysis of the effects is not necessary to find an infringement.

"This presumption is based on the serious nature of the restriction and on experience showing that restrictions of competition by object are likely to produce negative effects on the market and to jeopardize the objectives pursued by the Community competition rules."
"Settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies are an example of (...) potentially anticompetitive agreements, in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets."
Patent – Merely a "Probablistic" Right?

Bertold Bär-Bouyssière
Partner, DLA Piper
Competition Law
Brussels
The exclusionary power of the patent owner exists as long as the patent is not expired or invalidated.

The protection of IP rights should allow for derogation from EU internal market rules of free movement and from competition law.
"When granted by a public authority, an intellectual property right is normally assumed to be valid and an undertaking’s ownership of that right is assumed to be lawful. The mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right."

(AstraZeneca C-457/10)
"Decisive for the legal assessment in this case is therefore not only whether certain limitations on the generic undertaking's behaviour were part of the Agreements in question, but also, and particularly, whether those limitations had been paid for by the originator undertaking."
EU law does not ignore the many good reasons why parties in dispute over a patent may feel that a reverse-payment patent settlement is the best way out of a blocking situation.

The penultimate reason to prosecute reverse-payment patent settlements is that the originator pays for buying certainty and the generic accepts value for giving certainty.

Generally, in EU competition law, anything that reduces the uncertainty of a competitor's future behavior, including the unilateral passing on of commercially sensitive information, is viewed as unlawful.
Practical Impact of the New US Supreme Court Case

- What settlement deals can be made?
  - Deals regarding time
  - Deals regarding authorized generics
  - Deals paying small amounts to cover litigation
  - Deals regarding transfer of technology and know-how

- Will reverse-payment deals be made?
  - Cost and disruption caused by FTC/DOJ litigation
  - Reputational concerns
  - Retrying the case in court less knowledgeable regarding patents
  - Settlement agreements may require FTC/DOJ approval before binding
What Settlement Deals Can Be Made?

- Deals regarding time
  - Patent expires in 2020
  - Parties agree that generic company can enter the market in 2018

Can Pharmaceutical Companies Settle Patent Litigation without Pay-for-Delay Agreements?

Yes. From FY2004-FY2009, pharmaceutical companies filed a total of 218 final settlement agreements involving brand and generic companies. Seventy percent of those patent settlements – 152 – did not involve compensation from the brand to the generic combined with a delay in generic entry. This large number of settlements not involving compensation from the brand to the generic undermines brand and generic firms’ arguments that compensation is the only way to settle patent litigation. In fact, there are a variety of ways to settle litigation that do not involve these payments.

Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions
Federal Trade Commission | ftc.gov
An FTC Staff Study
January 2010
What Settlement Deals Can Be Made?

- Deals regarding authorized generics
  - Deals where the brand name agrees not to sell an authorized generic
  - Deals where the brand name appoints a second filer as the authorized generic to undermine the first filer’s sales
  - Deals where the brand name appoints the generic company as authorized generic distributor
  - Deals where the brand name can sell an authorized generic but pays a penalty for doing so
  - Deals where the generic is appointed authorized generic on a different drug
What Settlement Deals Can Be Made?

- Deals paying small amounts to cover litigation
  - Yes, FTC permits payment to cover the generic’s cost of litigation.
- Deals regarding transfer of technology and know-how
  - Generally not permitted, because seen as a payment.
Will Reverse-Payment Deals Be Made?

- Cost and disruption caused by FTC/DOJ litigation
  - FTC/DOJ engage in onerous discovery, since they do not face discovery obligations themselves.
  - Investigation uses up time of corporate employees better spent developing new products.

- Reputational concerns
  - Pharmaceutical companies want to appear to be ethical actors to physicians and patients.
  - Damage to reputation can hurt sales.
Retrying the case in court less knowledgeable regarding patents

- “Simply put, there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue—the question of patent validity—as part of a defense against an antitrust suit.” *FTC v. Actavis, Inc.*, slip op. at 11 (Roberts, C.J., dissenting).

- Example: *In re ABBOTT LABORATORIES NORVIR ANTI-TRUST LITIGATION*, 562 F.Supp.2d 1080 (N.D. Cal. 2008), *rev’d on non-patent grounds* 571 F.3d 930 (9th Cir. 2009)
  - Only a few pages devoted to patent invalidity, finding key invention for treating HIV invalid
  - Decision would have been reviewed by Ninth Circuit, a court having no patent expertise or access to technically-trained attorneys
Will Reverse-Payment Deals Be Made?

- Settlement agreements may require FTC/DOJ approval before binding

  “SEC. 1112. NOTIFICATION OF AGREEMENTS.

  (a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

  (1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA … and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.”

- “The Parties shall submit the Settlement Documents to the Federal Trade Commission Bureau of Competition (the “Commission”) and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice (the “DOJ”) as soon as practicable following the Effective Date and in no event later than ten (10) business days following the Effective Date.”
The tension between IP rights and competition law evolved in the past 25 years

- Ancient rule: IPRs as a safe harbor against antitrust claims
- Middle age: patent abuse
- Modern times: AstraZeneca, Lundbeck
- The future?
The Castle

Gualtiero Dragotti
Partner, DLA Piper
Patent Litigation
Milan
The Brick

CURRENTLY SPEAKING

Gualtiero Dragotti
Partner, DLA Piper
Patent Litigation
Milan

- Pioneer inventions, inventions, ancillary inventions
- Product patents
- Method patents
- Formulation and dosage patents
- Supplementary protection
Remedies?

- Patent litigation settlements must be reviewed by competition advisors
  - Understand the strength of each patent
  - Patent triage
  - Litigation path and strategy
  - The warning letters: the first step
  - Time to litigation
  - Pricing strategies
  - Global approach
Sectors

- The Life Science sector
  - Big players
  - High development costs
  - Heavy regulated sector
  - Controlled prices
  - Captive customers (sort of)

- The Technology sector

- Same story?
QUESTIONS

Carl Hittinger
Partner, DLA Piper
Anti-Trust
Philadelphia
carl.hittinger@dlapiper.com
+1 215 656 2449

Stuart E. Pollack
Partner, DLA Piper
Patent Litigation
New York
stuart.pollack@dlapiper.com
+1 212 335 4964

Paolo Morante
Partner, DLA Piper
Anti-Trust
New York
paolo.morante@dlapiper.com
+1 212 335 4813

Bertold Bär-Bouyssière
Partner, DLA Piper
Competition Law
Brussels
bertold.bar-bouyssiere@dlapiper.com
+32 2 500 1535

Gualtiero Dragotti
Partner, DLA Piper
Patent Litigation
Milan
gualtiero.dragotti@dlapiper.com
+39 02 80 618 514

Simon Uthmeyer
Partner, DLA Piper
Litigation & Regulatory
Sydney
simon.uthmeyer@dlapiper.com
+61 3 9274 5470