



Competition law, patent strategies and patent settlements

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- **A focus for antitrust enforcement following the Sector Inquiry**
- **Servier investigation ongoing**
- **Issue is ‘reverse payment’ settlements**
 - from patent holder to generic

‘as is shown by the enforcement action of the USA competition authorities, in particular the Federal Trade Commission, it might also be argued that settlements contain arrangements that could fall within the scope of competition rules’

Preliminary Report

- **Settlement presumed unlawful if**
 - there is a substantial reverse payment
 - generic entry is not immediate, and
 - there is no proof of any motive for the payment other than delayed generic entry

“it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent’s effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market.”

In re Cardizem (6th Cir)

“As a matter of economics, it will generally be most profitable if the brand and the generic firm avoid the possibility of competition and share the resulting monopoly profits”

Michael Kades, FTC

“[If] the patent holder makes a substantial payment to the challenger as part of the [settlement] deal, absent proof of other offsetting considerations, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable compromise”

Schering-Plough

- ***Schering-Plough* (Amicus Curiae brief)**
 - FTC presumption not appropriate
 - “an appropriate legal standard should take into account the relative likelihood of success of the parties’ claims, viewed ex ante.”
 - “[assessed in] a limited examination into the relative merits of the patent claims and other relevant factors surrounding the parties’ negotiations”
- **Post Varney appointment**
 - strongly support FTC line

- **Consistently rejected FTC line**
 - *Schering-Plough v. FTC* (11th Cir)
 - *In re Tamoxifen* (2nd Cir)
 - *In re Ciprofloxacin* (Fed. Cir.)
- **Settlements lawful if entry delayed only**
 - in relation to infringing products
 - for the life of the patent
- **Exceptions**
 - *In re Cardizem* (6th Cir)
 - fraud or bad faith

- **Public interest in settlements**
- **Difficulties in attributing payments**
- **Presumption of patent validity/Limited anti-competitive effect**
- **FTC counterfactual “untenable”**

- “the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable compromise”

Schering-Plough

- Continued litigation would “yield a greater prospect of competition”

FTC v Cephalon

- **FTC has continued to pursue cases**
 - *FTC v Cephalon* – ongoing
 - *FTC v Watson* – dismissed 23 February
- ***In re Ciprofloxacin* (2nd Cir)**
 - class action claim
 - Court of Appeal has requested DoJ opinion

- **No presumption of validity for settlements**
 - *Bayer v Sülhöfer*
- **Need for results from Sector Inquiry**
- **Record of EU Courts**
- **Broad approach to reverse payments (“value transfers”)**
 - including licenses and distribution deals

- “During the public consultation, some stakeholders expressed concern that all [reverse payment] settlement agreements ... were deemed anticompetitive ... any assessment ... would require an in-depth analysis”

Final Report, EU Sector Inquiry

- “[Commission] will not take the view *per se* that patent settlements are probably illegal”

Dominik Schnichels

- **Servier case being pursued**
- **Focus may be on cases involving**
 - delay beyond patent scope or term
 - bad faith or fraud
- **Approach similar to DoJ proposal?**
 - *Toltechs-Dorcet*
- ***In re Ciprofloxacin* (2nd Cir) could change things**

- **Avoid settlements that restrict generic entry outside patent term and scope**
- **Be wary of**
 - naked reverse payments
 - similar arrangements, eg royalty free licenses
- **Be extra careful if of internal documents indicating that patent is likely to be invalid**

Thank you