Legal Assessment of Patent Settlement Agreements Containing “Reverse” Payments

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Fordham IP Conference, New York, April 5, 2013
The EU Commission’s Lundbeck Case

- Objections issued against six settlement agreements concluded with four generic companies in 2002-2003

- Commission claims that these agreements restrict competition by object – no need to show anticompetitive effects

- Commission’s Statement of Objections points to a number of factors:
  - The transfer of value from Lundbeck to the generics (“reverse” payments)
  - The alleged “out-of-scope” character of the agreements
  - The alleged absence of final resolution of the dispute
  - The alleged absence of court litigation
  - The alleged existence of potential competition between Lundbeck and the generics
Legal Assessment

The Agreements Do Not Restrict Competition By Object

The Remaining Considerations In The SO Are Erroneous / Irrelevant
No Clear And Coherent Legal Standard For Review Of Patent Settlements

Lundbeck’s patents were weak / invalid

The reverse payment is “decisive”

Agreements went beyond the scope of patent rights

“True purpose” was to keep generics out of the market entirely

Agreements did not terminate any dispute but merely postponed generic entry

Generics = actual or potential competitors

Court litigation is a prerequisite for the legality of settlements

The Agreements restrict competition by object

It is unclear whether specific elements are decisive, or only a combination of them?
## No Objections Against All Reverse Payment Agreements

<table>
<thead>
<tr>
<th>Tillomed Agreement</th>
<th>Agreements Subject to SO</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Evidence of infringement</td>
<td>▪ Evidence of infringement</td>
</tr>
<tr>
<td>▪ Wording expressly prevents sale by generic of infringing products; no need to refer to preamble or annexes</td>
<td>▪ Wording + Context + Conduct show limitation to infringing products</td>
</tr>
<tr>
<td>▪ Explicit link to the Lagap litigation</td>
<td>▪ Link to ongoing disputes and extension linked to Lagap litigation</td>
</tr>
<tr>
<td>▪ Reverse payment</td>
<td>▪ Reverse payment</td>
</tr>
</tbody>
</table>

### This would tend to show that:
- Reverse payment is not “decisive” element
- The Scope-Of-The-Patent Test is key test
Today’s Objections Are Contradicted By Statements Made By The Danish Competition Authority In January 2004

DCA, Press Release of January 28, 2004

The [European] Commission considers that this is a gray Area and that it is unclear how close we are in this case to the black area. (translated from Danish)

It is therefore doubtful whether the agreements are restrictive of competition. Accordingly, the [European] Commission does not want to initiate proceedings against Lundbeck. (translated from Danish)
Almost 10 years (2003-2012) to attempt to formulate a legal standard for reverse payment settlements and to reach a preliminary view on the Agreements.

Objections Are Contradicted By The Duration Of The Investigation

- Oct. 2003: DCA deferred Agreements to European Commission
- 2005-2006: Inspections at Lundbeck’s premises; RFI
- Jan. 2008: Pharma Sector Inquiry
- 2009: Additional inspections
- Jan. 2010: Opening of proceedings; Several RFIs
- July 2012: Statement of Objections
“Object” Restrictions Must Be Restrictive By Their Very Nature As Confirmed By Experience Or Analysis

Guidelines on Article 101(3) TFEU

Agreements that “by their very nature,” are
“injurious to the proper functioning of normal competition”

Classification typically made based on:

AG Trstenjak in C-501/06 P
GlaxoSmithKline

“Existing experience” with certain types of agreements

and / or

C-8/08 T-Mobile Netherlands

In-depth analysis of content, objectives and “specific legal and economic context” of agreement
Put Simply, Restrictions Of Competition “By Object” Must Be Obvious

- “Obvious” violations = violations that are plain and indisputable

**T-374/94 European Night Services**

- “[A]greement[s] containing obvious restrictions of competition such as price-fixing, market-sharing or the control of outlets”

**AG Trstenjak in C-501/06 P GlaxoSmithKline**

- “With a restriction of competition by object, the negative interference with market conditions is so clear that the agreement can be presumed, without any detailed market analysis, to have a restrictive effect.”

However, no “existing experience” of reverse payment patent settlements and no obvious restrictive effect for settlements within the Scope-Of-The-Patent
The SO’s Reliance On Irish Beef Cannot Qualify As “Existing Experience”

C-209/07 Irish Beef

- It is revealing that SO relies on this case as the only and key guidance
- Industry-wide arrangement to reduce overcapacity in Irish beef processing market by paying processors to exit market
- Arrangements eliminated otherwise existing competition
- Beef processors held no patents, hence no right to exclude market entry

Lundbeck’s case

- Short-term agreements in pharmaceutical sector to address dispute between originator and generics
- No (lawful) competition would have existed absent the Agreements
- Lundbeck held valid patents giving it the right to exclude infringing products
  - Precludes comparison with Irish Beef


“If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court’s order. **This is not such a case, however, because one of the parties owned a patent**”
Object Restrictions Must Be Based On An Analysis Of Their Content And Objectives And On The Legal/Economic Context

The agreement is designed to achieve a legitimate commercial purpose, which is “neutral as regards competition or ... promotes competition” e.g., protect IPRs (C-27/87 Eruw-Jacquéry)

No Object Restriction If

Objective inability to restrict competition in individual case
- e.g., because no or insufficient competition to be restricted (AG Trstenjak in C-209/07 Irish Beef)

What the SO should have done:
- Identify an appropriate legal standard for review of patent settlements
- Review Agreements under that standard based on their content, objectives, and legal/economic context
The Appropriate Legal Standard for Patent Settlements Is The **Scope-Of-The-Patent Test**

Does the restriction fall within the temporal, territorial and substantive scope of the patent?
If YES: The agreement falls outside scope of Article 101 (1) TFEU

- Agreements within the scope of the patent do not restrict competition by object because:
  - *They have the legitimate purpose of enforcing a (valid) patent*
  - *They are objectively unable to restrict otherwise existing competition*
  - *The same result could be achieved through court proceedings*

The “market exclusion” flowing from the **patent settlement agreement** = The market exclusion flowing from the **patent**

Commission First, Second, and Third Reports on the Monitoring of Patent Settlements
(July 5, 2010; July 6, 2011; July 25, 2012)

by the originator company to the generic company. Other examples of possibly problematic agreements relate to settlements that contain restrictions beyond the exclusionary zone of the patent, meaning that they would reach beyond its geographic scope, its period of protection or its material scope, e.g. beyond the patent claims.
In all these cases we investigate whether the companies unlawfully extended their market exclusivity beyond the limits granted by their legitimate IPRs with the aim to delay the entry of generic products into the market.

We have already opened cases against VISA and the European Payments Council. Now we are considering whether part of the Court’s findings can be translated into rules applying to the whole market.

In the meantime, I expect MasterCard, Visa, domestic payment card schemes and, of course, banks to bring their fees and scheme rules in line with the judgment. The effects of the MasterCard judgment will be felt in national jurisdictions too. Enforcement procedures are ongoing before a number of national competition authorities and courts across the EU.

Finally, there is the possibility that victims of anticompetitive behaviour go to court to claim compensation for the damages incurred. I understand this is already happening regarding interchange fees.

So, there are many good reasons why payment card schemes and banks should align their practices with the judgment. And they should do so not only for fear of being found to have broken the law. Antitrust law is about preventing harm. It is not about punishment.

In all these cases we investigate whether the companies unlawfully extended their market exclusivity beyond the limits granted by their legitimate IPRs with the aim to delay the entry of generic products into the market.

Other indications of a strategic use of patents come from the mobile communications industry, which the media describe as a ‘patent war’. Let’s see why the war broke out in the first place.
The Scope-Of-The-Patent Test Is Reflected In EU Law

EU Law Support

Commission Notice on Patent Licensing Agreements (1962): “Les engagements ... ne sont pas visés ... par l’article 85, paragraphe 1, parce qu’ils sont couverts par le brevet”

C-320/87 Ottung: Obligation to pay royalties may restrict competition if it “purports to bind the licensee even after the expiry of the patent concerned”

C-193/83 Windsurfing: Only to the extent that such clauses are not “covered by the specific subject-matter of the patent ... the question arises whether the clause has as its object of effect the ... restriction ... of competition”
that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent. The issue in this...
The Agreements Meet The Scope-Of-The-Patent Test

**The Wording of Agreements**
- The Agreements restrict the sales of infringing products only
- Consistent with consent orders

**The Actual Conduct of Generics**
- Generics did not consider themselves prevented from marketing non-infringing citalopram
  - *e.g.*, Arrow searched for non-infringing sources of API and Alpharma said publicly that it would need non-infringing API to enter the market

**The Factual Context**
- No alternative non-infringing process
- 80+ generic companies in UK and 300+ in EEA could have launched non-infringing generic citalopram, had any been available
- Had any non-infringing process existed, generics could not have switched to it in 2002-2003
The Four Generics Were Not Actual Or Potential Competitors Of Lundbeck

- The generics had no **lawful** alternative products
- In any event, they had only limited marketing authorizations at the time the Agreements were concluded:

<table>
<thead>
<tr>
<th>Generic Party</th>
<th>Marketing authorization held as of conclusion of Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>GUK</td>
<td>Only Sweden and the UK – <strong>None in rest of EEA</strong></td>
</tr>
<tr>
<td>Arrow</td>
<td><strong>None in the UK and Denmark</strong> (N.A. for other countries)</td>
</tr>
<tr>
<td>Alpharma</td>
<td>Denmark, Finland, the Netherlands, Sweden – <strong>None in rest of EEA</strong></td>
</tr>
<tr>
<td>Ranbaxy</td>
<td><strong>None</strong></td>
</tr>
</tbody>
</table>
Legal Assessment

The Agreements Do Not Restrict Competition By Object

The Remaining Considerations Are Erroneous / Irrelevant
No Legal Reasons For Blanket Condemnation Of Reverse Payments

Reverse payments are neutral from a competition law perspective

- Infringement is independent of the parties’ financial incentives

  **C-403/04 Sumitomo**
  
  “As far as the existence of the infringement is concerned, it would not matter whether or not the conclusion of the agreement was in the commercial interest of [one of the parties]”

  **T-99/04 AC-Treuhand**
  
  whether payment creates incentive for one party to accept a restriction of its freedom of action (inherent in any contract) is irrelevant
Reverse Payments Aim At Avoiding The Irreversible Harm That Would Result From Infringing Entry, Absent A Timely Injunction

- **Uncertainty**
  - A patentholder can never be 100% certain that:
    - the validity of its patent will be upheld in court
    - the court will find the generic to infringe the patent

- **Significant time**
  - Litigating to obtain a preliminary injunction can involve significant time

- **Risk of irreversible harm**
  - An originator may suffer irreversible harm if infringing entry occurs before a preliminary injunction has been obtained
    - On the other hand, a generic will suffer only limited damages from being injunctions or found to infringe
    - → Asymmetry of risks

“Hold up” problem
Reverse payments reflect the imbalance in the parties’ bargaining positions.


ent. Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement. See, e.g., Cipro-


likely to lose but also for the side that is likely, but only likely, to win. A party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn. With four chambers of a seven-chamber revolver unloaded, a party pulling the trigger is likely (57% to 43%) to survive, but the undertaking is still one that can lead to undertaking.
The Tillomed Agreement also involved reverse payment

If payment is “decisive”, then why abandon objections against the Tillomed Agreement?

According to SO, payment attracts antitrust scrutiny only if it involves “considerable sum of money”. However:

- “considerable” remains undefined
- Legal test based on amount is unprecedented and would be a slippery slope
- In any event, it is not satisfied in this case: DCA press release 2004:

The [European] Commission is of the opinion that the amounts at issue in the Lundbeck case are of such a size that it is not possible to show plausibly that they concern compensation in order to keep a competitor out of the market. It is therefore doubtful whether the agreements are restrictive of competition. Accordingly, the [European] Commission does not want to initiate proceedings against Lundbeck. (translated from Danish)
Lundbeck’s Patents Were Wrongly Assumed To Be Invalid, “Weak”, Or Not Infringed

- Lundbeck’s patents were valid
  - Crystallization Patent
    - Validity of all relevant claims upheld by EPO in 2009
    - Expiry date 2020
  - Iodo Process Patent
    - Validity never challenged
    - Expiry date 2019
  - Amide Process Patent
    - Validity never challenged
    - Expiry date 2018

- These assumptions are incorrect
- There was unambiguous scientific evidence of infringement by generics
- There was no valid reason to assume that same result could not have been achieved through the enforcement of Lundbeck’s patents in court
The Commission Cannot “Second-Guess” Patent Validity And The Outcome Of Patent Litigation

The Commission has no legal authority to decide on patent validity:
- C-24/67 Parke, Davis and Co.: Patent recognition and enforcement is a matter for national law
- T-321/05 AstraZeneca: Patents are presumed to be valid once granted

The Commission is not well-placed to assess the possible outcome of patent litigation, which is notoriously unpredictable


There are other reasons to reject the FTC’s approach. It would require an after-the-fact calculation of how “likely” a patent holder was to succeed in a settled lawsuit if it had not been settled. Predicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous an enterprise to serve as a basis for antitrust liability and treble damages. See Valley Drug, 344 F.3d at 1308 ("Patent
Failure To Initiate Court Litigation Is Irrelevant, Contrary To The SO’s Allegation

- There would be a significant paradox if the legality of settlement agreements depended on prior initiation of litigation: Settlements **aim precisely at avoiding litigation**
  - National rules of civil proceedings (*e.g.*, UK) promote settlement route
  - EU legislation favors out-of-court dispute resolution, *e.g.*, Directive 2008/52/EC on mediation in civil and commercial matters

- The SO itself clearly accepts that settlements can originate from mere dispute
A Genuine Dispute – As Opposed To Litigation – Is Sufficient

As will be explained in more detail in subsequent sections, the starting point for companies to conclude a settlement is that they disagree at the outset of the litigation/trade opposition about whether the patent of the originator company is valid and/or whether the manufacturing or sales activities of the generic company infringe the originator company's patent. As in any other area of commercial activity, such settlements can offer significant advantages to all parties involved. In the context of the public consultation, some stakeholders expressly supported this view stating that a settlement in many instances is an efficient way for parties to end a dispute.

In total, 207 patent settlement agreements were submitted. Figure 98 breaks down their number on a yearly basis. In the period 2000 – 2002, the number was lower than for the last six years in which, on average, some 25-30 patent settlement agreements were concluded every year in the EU; the exception was the year 2005, when 53 settlements were concluded.

In Remia v Commission, the Court stated, with regard to non-compétition clauses included in an agreement for the

Opinion of AG Darmon in Case 65/86 Bayer v. Sühlhöfer

and last criteria. First of all, giving a special status to settlements putting an end to litigation might give rise to fictitious disputes whose aim was to achieve an otherwise prohibited agreement. It would then be
The Agreements Were Linked To Genuine Disputes

<table>
<thead>
<tr>
<th>Generic</th>
<th>Warning letter(s)</th>
<th>Admission or serious concerns</th>
<th>Meetings to resolve dispute</th>
<th>Visit at premises</th>
<th>Litigation</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>GUK</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>Both parties explored whether to initiate litigation</td>
<td>Intervention of the Hamburg Customs Authority to seize products for analysis</td>
</tr>
<tr>
<td>Arrow</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
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<td>✔</td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
</tbody>
</table>
Short-Term Settlement Agreements Are Perfectly Lawful

- **No obligation to give up exclusivity rights** before expiry of patents, *e.g.*:
  - by agreeing on date for generic entry, or
  - by undertaking to refrain from infringement proceedings

- Short-term settlement agreements are **less restrictive than “final” settlements**
  - Final settlements typically include no-challenge clause
  - Short-term settlements can lead to earlier generic entry

The Agreements Were Tied to Patent Litigation That Was Decisive To Resolve The Underlying Disputes

- GUK Agreements: Designed to “clear the way” and then tied to Lagap litigation
- Arrow and Alpharma Agreements: Tied to litigation against Tiefenbacher, then Lagap
- Ranbaxy Agreement: Tied to Lagap litigation
Intent To Enforce A Valid Patent Is Legitimate, Contrary To The SO’s Suggestion

SO Mischaracterizes Lundbeck’s Intent To Defend Its Patents

- SO relies on a few selected documents to claim that Agreements reflected illegitimate strategy to restrict competition
- SO completely ignores that Lundbeck:
  - Held valid patents
  - Had evidence of infringement
- No evidence that Lundbeck suspected invalidity of patents or tried to mislead patent offices to obtain them (≠AstraZeneca)
- No evidence of generics’ anti-competitive intent

Evidence Of Subjective Intent Irrelevant Absent Fraud In Obtaining A Patent

- SO recognizes that intent cannot make otherwise lawful agreements unlawful
  - “What matters for a restriction of competition by object is whether the agreements in question objectively aimed at restricting competition” (para. 747)