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Details Of The European Commission's Legal Analysis Of 'Reverse Patent Settlement Agreements' Revealed

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The recently published landmark decision concerning the ***Lundbeck citalopram*** case revealed the details of the ***European Commission ("Commission")***'s competition law analysis regarding reverse patent settlement agreements.

In the years 2002 and 2003, the *Danish pharmaceutical company Lundbeck* concluded six agreements with four companies (*Merck KGaA/Generic UK ("Merck"), Arrow, Alpharma and Ranbaxy)* aimed at delaying market entry of generic versions of its blockbuster antidepressant citalopram. The product was sold under the brand name Cipramil and was referred to by Lundbeck as its "***golden egg***". In its legal assessment, the Commission essentially looked at (i) the precise economic and legal context leading to each agreement, (ii) the actual content and objectives of each agreement and (iii) each party's subjective intentions in order to examine whether they matched the analysis of the objective elements of the first two steps (para. 735).

In order to identify whether each agreement had the potential of restricting competition 'by its very nature', the Commission focused essentially on the following elements:

1. **Lundbeck's overall business strategy**

According to the Commission, Lundbeck adopted the following measures to avoid litigation and prevent generic companies from entering the generic citalopram market:

- *Patenting processes to manufacture citalopram:* Lundbeck first of all filed for patent protection for each aspect of the manufacturing and production methods. This strategy was called the "process patent defence" and was revealed on the basis of Lundbeck's internal documents. The aim was to deter manufacturers of Active Pharmaceutical Ingredients ("API") from starting to produce generic citalopram and refrain from entering the citalopram market;

- *Intervening in marketing authorisation procedures for generic citalopram medicines:* Because

it was uncertain as to the effective protection provided by its crystallisation patent, Lundbeck took steps to prevent or delay marketing authorisations for generic citalopram medicines;

- *Eliminating the competitive threat of upcoming citalopram API producers:* Lundbeck's strategy also focused on citalopram API producers. Although it hesitated to opt for a "litigation approach" and use its patents covering manufacturing processes to stop API producers, Lundbeck initially decided to adopt a more collaborative approach referred to as the "deal making strategy".

2. 'At least potential competitors'

Basing itself on the concept of potential competition as developed by the EU Courts, the Commission described some of the specific characteristics of the pharmaceutical sector and considered that potential competition starts (1) when generic producers that want to launch a generic medicine upon expiry of the exclusivity of the compound patent (or underlying API producers) begin developing a "*commercially viable production process leading to a product that meets regulatory requirements*" and (2) when suppliers of generic medicines to the targeted markets prepare for actual generic entry by following different steps, the first of which is to apply for marketing authorisations. (para. 616)

The fact that legal challenges of Lundbeck's process patents were possible and that both Lundbeck and the generic companies were in fact assessing the option of challenging the process patents, clearly showed that the parties were at least potential competitors. Generic companies moreover had actual business plans in place to sell generic citalopram in markets in the EEA, which reinforced the Commission's conclusion on this point.

3. The generic companies' commitments

The generic companies committed themselves to limit, for the duration of the agreements, their independent efforts to enter one or more EEA markets with generic citalopram medicines, thus going beyond the scope of Lundbeck's process patents. The most notable commitment was that they agreed, in exchange for the value transferred, not to sell *any* citalopram even citalopram not manufactured based on a patented process.

4. The concept of 'value transfer'

Each agreement was related to a transfer of (significant) value from Lundbeck to the generic company. This substantially reduced the incentives of the generic companies to independently pursue their efforts to enter on one or more EEA markets with generic citalopram. Although the Commission did not provide detailed criteria for assessing value transfers between originator and generic companies, it did explain why it considered value transfers problematic in this context (para 604).

The Commission assessed that the transfer of value was directly linked to the acceptance by each generic company of the limitations on entry in the respective agreements.

5. The parties' intentions

For each agreement, the Commission also looked at the parties' intentions regarding the aim of the respective agreements and concluded that each of the parties involved knew, or should have known, that their agreement was anticompetitive.

6. Additional key factors

Finally, the Commission also took into account the following:

- the sum paid by Lundbeck to the generic companies was based upon the generic company's expected turnover or profit, had it successfully entered the market;
- Lundbeck could not have prevented or delayed entry through the enforcement of its process patents;
- the obligations on the generic companies went beyond the rights usually granted to holders/ licensors of process patents; and
- the agreements did not contain any commitment from Lundbeck to refrain from infringement proceedings if the generic company entered the market with generic citalopram products after expiry of the agreement. This made market entry by the generic companies post-expiry rather uncertain as they had no guarantee that Lundbeck would not sue them after all for infringement of the process patents (para. 662).

7. Efficiency defence under Article 101(3) TFEU

The Commission also assessed the parties' efficiency defence arguments but concluded that no party submitted the required evidence to justify that one or more of the competitive restrictions could be exempted under Article 101 (3) TFEU.

On the basis of the above, the Commission concluded that the agreements were anticompetitive 'by object' and could not be individually exempted.

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