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Merger Control Trends In Pharma

Cleary Gottlieb Pharmaceutical, Biotech and Healthcare Group

June 2022

Merger Control Trends In Pharma

1	There are 150+ jurisdictions with a mandatory merger control regime. Global pharma deals are likely to trigger dozens of filings worldwide.
2	Merger pharma enforcement has become less permissive in recent years: 1 in every 5 EU notified pharma deals in the last five years required remedies.
3	Agencies increasingly consider narrow pharma markets at the ATC4/molecule level and take a microscopic look at any overlaps in lines of research/pipelines.
4	Substantive analysis is driven by product overlaps: remedies likely in deals between close competitors with high shares and few alternatives.
5	Agencies are focused on ways to ensure that strategic pharma acquisitions (*e.g., Illumina/Grail*) do not escape merger review.
6	Agencies focus on remedy design and vet divestiture buyers carefully, especially for pipeline remedies.

Merger Pharma Enforcement Has Become Less Permissive

EC has reviewed **57** pharmaceutical sector transactions in the **last 5 years**

44

Unconditionally cleared in Phase I

11

Conditionally cleared in Phase I

2

Referred to Phase II investigation

- *Illumina/Grail* (ongoing)
- *J&J/Tachosil* (withdrawn)

Focus On Narrow Product Markets

STARTING POINT

ATC 3 classification, which groups pharmaceuticals based on their intended use.

— But EC frequently also looks at molecular composition, dosage, pharmaceutical form, route of administration, and packaging and pricing, and considers markets at the ATC4/molecule level.

Other considerations:

Generics / Biosimilars

Treated as competitors of originator drugs, once patents have expired (EC looks at the molecule)

Prescription / OTC

Treated as distinct markets, though with exceptions, *e.g.*, where drugs have dual status (*Sanofi-Aventis/Zentiva*)

Pipeline Products

Market definition based on characteristics of treatment in development and intended therapeutic use

GEOGRAPHIC MARKET

National for pharmaceuticals and EEA-wide for pipeline products.

Microscopic Look At The Overall Pipeline Portfolio

PIPELINE: HISTORICAL APPROACH

Pipelines relevant as of Phase III clinical trials.

PIPELINE: CURRENT APPROACH

In a number of recent cases, the EC required:

— A complete overview of all lines of research/pipeline projects, regardless of the stage of the development.

— Divestiture of pipeline projects.

— An up-front buyer, with a close scrutiny of the ability and incentive to bring the pipeline to market.

Substantive Analysis Driven By Traditional Overlaps

Substantive merger analysis in pharma remains focused on traditional product/innovation overlaps, and less so on vertical supply relationships or activities across markets.

UNILATERAL EFFECTS – PRODUCT OVERLAPS	Three or fewer large players post-transaction	Parties' combined shares >35%
	Merging parties are close competitors	Pipeline and commercial product overlap

VERTICAL	— One merging party is an essential supplier or customer for the other party's competitors
CONGLOMERATE	— Combined entity would have high shares in multiple products with common customers
COORDINATED EFFECTS	— Markets are concentrated, products are commoditized, prices are transparent

Extending Jurisdiction To Capture Strategic Deals

EU merger control jurisdiction has traditionally been based on EU/national turnover-based thresholds.

EC now allows Member States to refer deals for EC review even if Member States have no jurisdiction if the deal involves "*firms that play or may develop into playing a significant competitive role on the market at stake despite generating little or no turnover*".

ILLUMINA/GRAIL: EC asserted jurisdiction even though Grail has no existing EU business.

- Illumina appealed the EC's assertion of jurisdiction and EC interim measures that sought to prevent the deal's closing pending EC merger review.
- Illumina meanwhile closed the deal to avoid a contractual termination fee, which prompted a separate EC gun-jumping investigation.
- EU General Court judgment on EC jurisdiction is expected in July 2022.

Increased Focus On Remedy Design

EC concerned that Takeda would discontinue the development of Shire's new anti-integrin treatment.

Takeda agreed to divest Shire's pipeline drug to a purchaser with an incentive to develop it.

18 months after the EC decision and prior to completing the divestment, EC agreed to waive the pipeline remedy in its entirety due to "changed market circumstances":

— Studies of Shire's pipeline drug had yielded negative safety and efficacy results.

— Unforeseeable difficulties in recruiting patients for Shire's clinical trials.

— Emergence of promising superior new drugs.

— EC waiver of remedies historically rare, though 5 waivers in the past few years.

— The Takeda waiver is fact-specific and unlikely to signal a trend of future EC remedy waivers in pharma.

— Instead, the EC may adopt a stricter stance in negotiating pipeline remedies.

Merger Control – Practical Take Aways

1	Undertake a preliminary assessment as early as possible: consider overlaps under narrow products markets and across pipeline portfolios.
2	Running a complex deal requiring many filings is challenging. Manage business expectations as to the length and intensity of merger review.
3	Many merger filings are data/document-heavy. Early preparation is essential.
4	Develop and articulate a pro-competitive deal rationale at the outset. Manage internal document creation.
5	Negotiating and drafting remedies is a major work stream. Plan early.

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