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# Cleary's Pharma Bites

## Excessive Pricing

Cleary Gottlieb Pharmaceutical, Biotech and Healthcare Group  
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# Excessive Pricing – Background

1

Excessive pricing cases have historically been rare due to the reluctance of antitrust agencies to engage in price regulation.

2

However, there has been a proliferation of excessive pricing cases in the pharma sector in the post-pandemic period (12 cases in 2021-2023).

3

Antitrust enforcement focuses on the pricing of off-patent and orphan drugs.

4

Common feature is a substantial price hike without a reasonable objective justification.

# Excessive Pricing In Pharma – Overview (1)

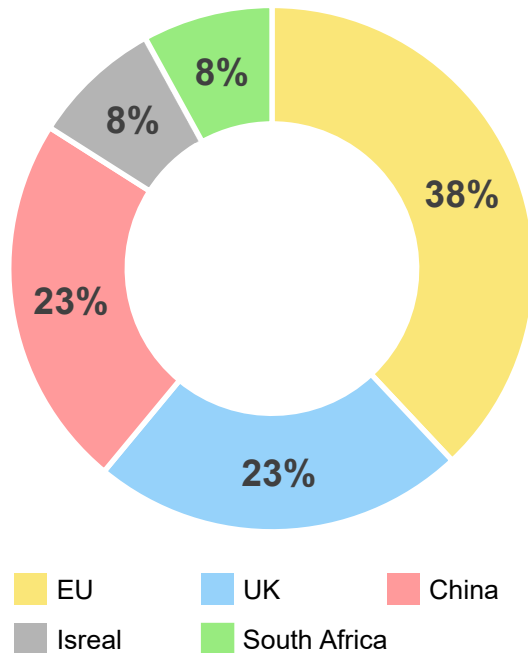
COUNTRY	CASE	PRODUCT	PRICE	OUTCOME
EU	<i>Aspen</i> (2021)	Off-patent	> costs by ~300%	Supply & reduced-price commitment
Italy	<i>Leadiant Biosciences</i> (2022)	Orphan drug	+961%	€3.5 million ( <i>pending appeal</i> )
Spain	<i>Leadiant Biosciences</i> (2022)	Orphan drug	+1,386%	€10.3 million ( <i>pending appeal</i> )
Netherlands	<i>Leadiant Biosciences</i> (2021)	Orphan drug	+600%	€19.5 million ( <i>pending appeal</i> )
Denmark	<i>CD Pharma</i> (2018)	Off-patent	+2,000%	Order to cease and desist applying excessive prices
UK	<i>Pfizer/Flynn</i> (2022)	Off-patent	+2,400%	£70 million ( <i>pending appeal</i> )
	<i>Advanz Pharma</i> (2021)	Off-patent	+6,021%	£101 million ( <i>pending appeal</i> )
	<i>Auden/Actavis</i> (2021)	Orphan drug	+10,000%	£155 million ( <i>pending appeal</i> )
China	<i>Tianjin Jinyao Pharmaceutical</i> (2023)	Off-patent	+1,400%	€3.7 million
	<i>NEPG</i> (2023)	Off-patent	+400%	€18.1 million
	<i>Shangqiu New Pioneer Pharmaceutical</i> (2021)	Off-patent	+2,105%	€1.4 million
Israel	<i>MBI Pharma (Leadiant)</i> (2022)	Orphan drug	+515%	€2.2 million ( <i>pending appeal</i> )
South-Africa	<i>Roche</i> (2022)	Patent	>200% the price of equivalent treatment	Referral to Competition Tribunal

\* For completeness, the French competition authority issued an excessive pricing decision in the healthcare waste area in *Sanicorse/Cesarini*, which was recently annulled by the French Supreme Court. The decision does, though, indicate FCA's appetite in this area.

# Excessive Pricing In Pharma – Overview (2)

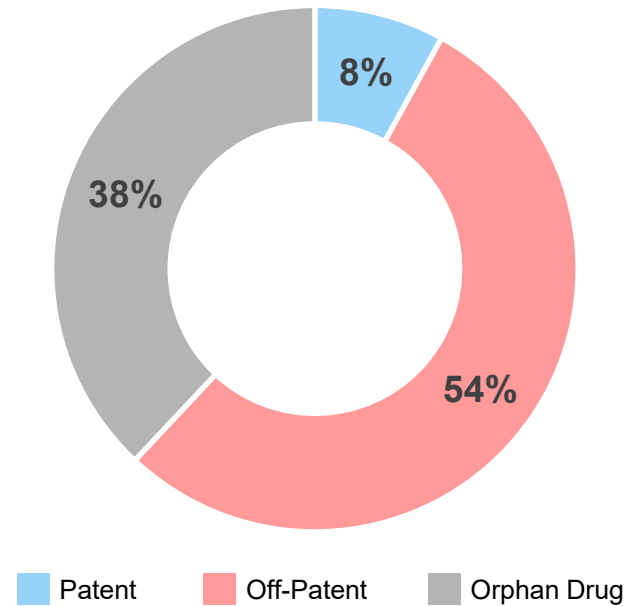
## REGION

~2/3 of the recent excessive pricing cases were brought by antitrust agencies in **EU/UK**.

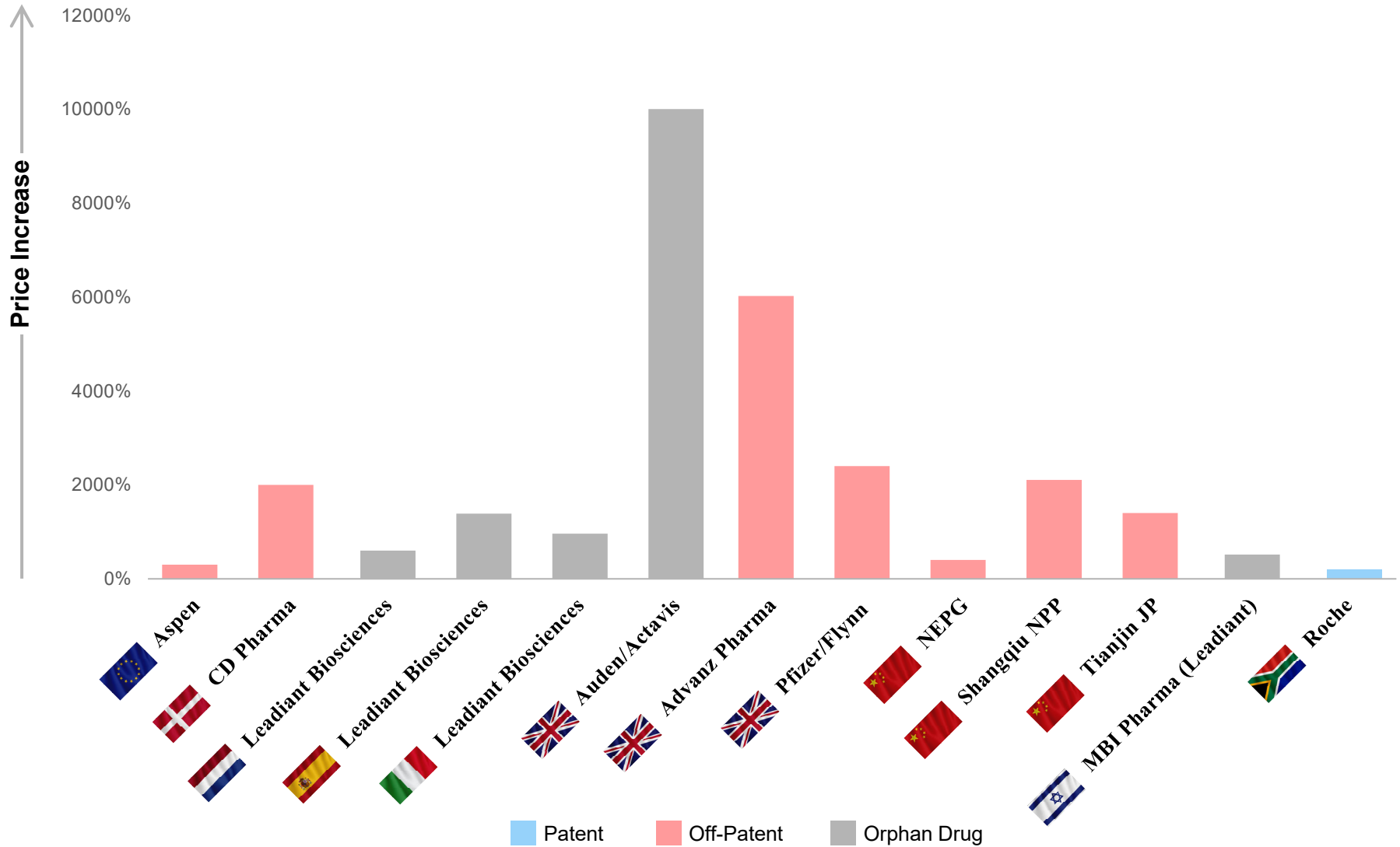


## PRODUCT

Enforcement focuses on the pricing of **off-patent** and **orphan** drugs.



# Excessive Pricing In Pharma – Overview (3)



# EU – *Aspen*



## FACTS

- Aspen's prices of off-patent cancer medicines > costs by ~300%; average EEA profitability 3x higher than comparable peers.
- To push higher prices, Aspen threatened to de-list or withdraw the medicines.

## SUBSTANTIVE TEST

- The EC established excessiveness by assessing Aspen's prices in relation to (i) Aspen's accounting data, and (ii) profit levels of comparable peers.

## OUTCOME

- No fine but Aspen committed to a 10-year supply subject to a reduced (73% on average in the EU) and fixed price ceiling.
- Aspen not allowed to withdraw supply for at least 5 years.

## CONTEXT

- First EU excessive pricing precedent in the pharma sector.

# UK – Pfizer/Flynn



## FACTS

- Debranding: Pfizer transferred its UK MA for “Epanutin” to Flynn without the associated trademark.
- Flynn’s newly genericized product was not subject to price controls and dramatically increased its price (NHS cost increased from £2M to £50M).

## SUBSTANTIVE TEST

- The CMA established excessiveness by comparing Pfizer’s prices with a theoretical benchmark of “cost plus 6%”.

## OUTCOME

- £70 million fine (*under appeal before the CAT*)

## CONTEXT

- The CMA actively pursues excessive pricing cases in pharma – 3 matters in recent years.

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# China



## FACTS

— Three pharmaceutical companies sharply increased prices of off-patent products by 400% to 2,105%.

## SUBSTANTIVE TEST

— The SAMR considered sudden price increases excessive in the face of stable costs.

## OUTCOME

— Fines ranging from €1 million to €18 million.

## CONTEXT

— Excessive pricing in pharma is one of SAMR's stated enforcement priority.



# Orphan Drug Case Study



## FACTS

- CDCA is an orphan medicine treating a rare metabolic disorder.
- Price increases of +515% to +1,386%.

## SUBSTANTIVE TEST

- NCAs established excessiveness by comparing prices with costs.
- Leadiant's internal documents showed a strategy of targeting the maximum price customer was willing to pay irrespective of the product's costs.

## OUTCOME

- Fines ranging from €2M to €20M in Italy, Israel, the Netherlands, and Spain.
- Case dismissed in Belgium because alternatives were available through the practice of compounding by pharmacies and hospitals.

## CONTEXT

- Due to their importance, orphan drugs are likely to attract scrutiny – 5 investigations in Europe in recent years.

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# Practical Take Aways

**1**

There is increased appetite to investigate substantial price increases of pharma products.

**2**

It is advisable to carefully consider substantial price changes, particularly in the context of acquiring new products or removal from price regulation.

**3**

Substantial price increases should be objectively justified and properly documented.



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